In the United States Court of Appeals for the District of Columbia Circuit

DOCTORS FOR DRUG POLICY REFORM; BRYON ADINOFF, DR.,

Petitioners

ν.

DRUG ENFORCEMENT ADMINISTRATION; ANNE MILGRAM, IN HER OFFICIAL CAPACITY AS ADMINISTRATOR OF THE UNITED STATES DRUG ENFORCEMENT ADMINISTRATION,

Respondents

On Petition for Review of Orders of the Drug Enforcement Administration (Oct. 28, 2024 and Nov. 25, 2024)

PETITIONERS' APPENDIX VOLUME 2 OF 6 App.498 to App.690

> Austin T. Brumbaugh D.C. Circuit Bar No. 65727 YETTER COLEMAN LLP 811 Main Street, Suite 4100 Houston, Texas 77002 713-457-3099

Counsel for Petitioners

TABLE OF CONTENTS

DATE	DESCRIPTION	PAGE
	Orders and Rulings	
	Volume 1	
2024-12-06	Order Denying Motion to Stay	App.1
2024-10-28	Order Selecting Participants	App.7
2024-11-25	Bryon Adinoff, M.D. Rejection Letter	App.10
2023-08-29	Recommendation of the Department of Health and Human Services to the Drug Enforcement Administration	App.11
2024-04-11	Office of Legal Counsel Memorandum Opinion for the Attorney General, 48 Op. O.L.C.	App.261
2024-05-21	Notice of Proposed Rulemaking, 89 FR 44597-01	App.299
2024-08-29	Notice of Hearing on Proposed Rulemaking, 89 FR 70148-01	App.325
2024-09-26	Doctors for Drug Policy Reform Request to Participate in Hearing	App.327
2024-10-31	Preliminary Order	App.333
2024-11-19	Order re Standing, Scope, and Prehearing Procedures	App.343
2024-11-21	Order Denying Motion to Intervene	App.390
2024-12-04	Prehearing Ruling	App.394
2025-01-13	Order Regarding Village Farms International Hemp for Victory and OCO et al.'s Motion for Reconsider	App.404

DATE	DESCRIPTION	PAGE
	Requests to Participate and Agency Responses	
2024-02-28	Association of Federal Narcotics Agents Supporting Paper	App.411
2024-06-01	Request by International Academy on the Science and Impact of Cannabis	App.415
2024-06-04	Request by Khurshid Khoja (Greenbridge Corporate Counsel, P.C.	App.418
2024-06-11	Request by Sage Endoom Cannablisshum	App.423
2024-06-13	Request by Aubree Adams	App.431
2024-06-15	Request by Heidi Anderson-Swan	App.432
2024-06-16	Request by David Heldreth	App.473
2024-06-16	Request by National Drug & Alcohol Screening Association	App.443
2024-06-16	Request by Panacea Plant Sciences c/o David Heldreth	App.460
2024-06-17	Request by Bryn Spejcher	App.466
2024-06-17	Request by Ed Wood	App.467
	Volume 2	
2024-06-17	Request by Perkins Coie on behalf of American Trade Association for Cannabis and Hemp	App.498
2024-06-17	Request by Smart Approaches to Marijuana	App.500
2024-06-17	Request by Association of State Criminal Investigative Agencies	App.504
2024-06-18	Request by Association of Federal Narcotics Agents	App.507

DATE	DESCRIPTION	PAGE
2024-06-18	Request by Cannabis Industry Victims Educating Litigators	App.508
2024-06-18	Request by Coalition for Patient Rights	App.510
2024-06-19	Request by Bryan Krumm	App.526
2024-06-19	Request by Former DEA Administrators	App.536
2024-06-19	Request by Minority Cannabis Business Association	App.538
2024-06-19	Request by Phillip Drum	App.540
2024-06-19	Request by Tennessee Bureau of Investigation	App.542
2024-06-19	Request by United Empowerment Party	App.544
2024-06-20	Request by Doctors for Drug Policy Reform	App.548
2024-06-20	Request by Devan Maurice Dupuis and Nicholas Barreto	App.593
2024-06-20	Request by Lori Robinson	App.597
2024-06-20	Request by National Transportation Safety Board	App.599
2024-06-20	Request by South Carolina Attorney General and Various Other Attorneys General	App.601
2024-06-20	Request by United States Cannabis Coalition	App.604
2024-06-26	Request by Nicole Ricci	App.606
2024-07-19	Request by University of California San Diego Center for Medicinal Cannabis Research	App.611
2024-08-26	Request by Shane Gallichio	App.612
2024-08-29	Request by Brian Austin	App.613

DATE	DESCRIPTION	PAGE
2024-09-16	Request by Emily Fisher, CEO, Leafwell, Inc.	App.688
2024-09-17	Request by August Wakat	App.689
2024-09-18	Request by American Academy of Child and Adolescent Psychiatry	App.690
	Volume 3	
2024-09-18	Request by Bryn Spejcher	App.691
2024-09-18	Supplement by Phillip Drum	App.715
2024-09-20	Request by Cannabis Law PA	App.720
2024-09-20	Request by Drug Enforcement Association of Federal Narcotics Agents	App.723
2024-09-20	Request by Minorities for Medical Marijuana	App.724
2024-09-22	Request by Derek Shirley	App.740
2024-09-23	Request by Drug Enforcement Association of Federal Narcotics Agents	App.742
2024-09-23	Request by Bryan Krumm	App.744
2024-09-23	Request by Pharmacists Cannabis Coalition of California	App.754
2024-09-24	Request by The Doc App	App.756
2024-09-25	Supplement by Aubree Adams	App.758
2024-09-25	Supplement by Aubree Adams	App.761
2024-09-25	Request by Curio Wellness	App.771
2024-09-25	Request by Heidi Anderson	App.775

DATE	DESCRIPTION	PAGE
2024-09-30	Request by American Academy of Hospice and Palliative Medicine	App.950
2024-09-30	Request by American Psychological Association	App.952
2024-09-30	Request by Andrew DeAngelo	App.954
2024-09-30	Request by Ari Kirshenbaum, PhD	App.958
	Volume 4	
2024-09-30	Request by Association of American Railroads	App.959
2024-09-30	Request by BayMedica, LLC and Greenbridge Corporate Counsel, P.C.	App.960
2024-09-30	Request by Coalition for Patient Rights	App.973
2024-09-30	Request by Coss Marte	App.975
2024-09-30	Request by Compassion Center by Stormy Ray	App.976
2024-09-30	Request by Dennis Schuller	App.978
2024-09-30	Request by Drug Policy Alliance by Cat Packer	App.979
2024-09-30	Request by Ellen Brown	App.982
2024-09-30	Request by Erin Kirk	App.983
2024-09-30	Request by Esaia Gonzalez	App.984
2024-09-30	Request by Green Thumb Industries Inc.	App.988
2024-09-30	Request by Jasmine Montoya	App.1050
2024-09-30	Request by Jason Greninger	App.1054
2024-09-30	Request by Jordan Smith	App.1056

DATE	DESCRIPTION	PAGE
2024-09-30	Request by Karen O'Keefe	App.1057
2024-09-30	Request by Khurshid Khoja and BayMedica	App.1077
2024-09-30	Request by Last Prisoner Project	App.1090
2024-09-30	Request by Michael Doyle	App.1096
2024-09-30	Request by Natalie P. Hartenbaum, MD, MPH	App.1098
2024-09-30	Request by National Cannabis Industry Association	App.1104
2024-09-30	Request by National Sheriffs Association	App.1108
2024-09-30	Request by Nicholas Barreto	App.1112
2024-09-30	Request by Nick Richards, GreenspoonMarder	App.1116
2024-09-30	Request by National Organization for the Reform of Marijuana Laws (NORML)	App.1120
2024-09-30	Request by New York Office of Cannabis Management	App.1163
2024-09-30	Request by Patrick Oglesby	App.1171
2024-09-30	Request by Perkins Coie on behalf of American Trade Association for Cannabis and Hemp	App.1174
2024-09-30	Request by RTI International	App.1374
2024-09-30	Request by Russell Palmer	App.1374
	Volume 5	
2024-09-30	Request by Sensible Colorado	App.1380
2024-09-30	Request by Sisley Research Institute	App.1424
2024-09-30	Request by State of Colorado	App.1427

DATE	DESCRIPTION	PAGE
2024-09-30	Request by State of Nebraska	App.1430
2024-09-30	Request by Steph Sherer for Americans for Safe Access Foundation	App.1434
2024-09-30	Request by Stephen Mandile	App.1436
2024-09-30	Request by Students for Sensible Drug Policy	App.1437
2024-09-30	Supplement by Drug Enforcement Association of Federal Narcotics Agents	App.1440
2024-09-30	Request by T. Christopher Wright	App.1442
2024-09-30	Supplement by Tennessee Bureau of Investigation	App.1444
2024-09-30	Request by Training Marbles, Inc.	App.1447
2024-09-30	Request by United States Cannabis Coalition	App.1449
2024-09-30	Request by Village Farms International Inc.	App.1452
2024-10-08	Request by Walt A. Sanders	App.1458
2024-10-09	Request by Jeffrey Faatz	App.1460
	Request by Cannabis Bioscience International Holdings	App.1461
	Request by Equity Trade Network	App.1464
	Request by Jahan Marcu	App.1466
	Request by Kenneth Finn	App.1468
	Request by Michael Rountree	App.1472
	Request by Patrick Oglesby	App.1475

DATE	DESCRIPTION	PAGE
2024-10-28	Ari Kirshenbaum Acceptance Letter	App.1523
2024-10-28	Aubree Adams Rejection Letter	App.1524
2024-10-28	BayMedica, LLC Rejection Letter	App.1525
2024-10-28	Bryn Spejcher Rejection Letter	App.1526
2024-10-28	Cannabis Industry Victims Educating Litigators Acceptance Letter	App.1527
2024-10-28	Cannabis Law PA (Attn: Judith Cassel) Rejection Letter	App.1528
2024-10-28	Cannabis Law PA (Attn: Micah Bucy) Rejection Letter	App.1529
2024-10-28	Community Anti-Drug Coalitions of America Acceptance Letter	App.1530
2024-10-28	Corey Burchman, M.D. (Hemp for Victory) Acceptance Letter	App.1531
2024-10-28	Curio Wellness Rejection Letter	App.1532
2024-10-28	Darinia Douchi, M.D. (Hemp for Victory) Acceptance Letter	App.1533
2024-10-28	Drug Enforcement Association of Federal Narcotics Agents Acceptance Letter	App.1534
2024-10-28	Ellen Brown Acceptance Letter	App.1535
2024-10-28	Erin Kirk Acceptance Letter	App.1536
2024-10-28	Full Spectrum Inc. Rejection Letter	App.1537
2024-10-28	Heidi Anderson-Swan Rejection Letter	App.1538
2024-10-28	International Academy on the Science & Impact of Cannabis Acceptance Letter	App.1539

DATE	DESCRIPTION	PAGE
2024-10-28	International Association of Chiefs of Police Acceptance Letter	App.1540
2024-10-28	Jahan Marcu Rejection Letter	App.1541
2024-10-28	Jason Castro Rejection Letter	App.1542
2024-10-28	Jeffrey Fatz Rejection Letter	App.1543
2024-10-28	John Jones, Cannabis Bioscience International Holdings Acceptance Letter	App.1544
2024-10-28	Kenneth Finn, MD Acceptance Letter	App.1545
2024-10-28	Natalie Hartenbaum Rejection Letter	App.1546
2024-10-28	National Cannabis Industry (Aaron Smith) Acceptance Letter	App.1547
2024-10-28	National Cannabis Industry (Michelle Rutter) Acceptance Letter	App.1548
2024-10-28	National Drug & Alcohol Screening Association Acceptance Letter	App.1549
2024-10-28	National Sheriff's Association Acceptance Letter	App.1550
2024-10-28	National Transportation Safety Board Acceptance Letter	App.1551
2024-10-28	Pharmacists' Cannabis Coalition of California Rejection Letter	App.1552
2024-10-28	Phil Molloy Rejection Letter	App.1553
2024-10-28	Phillip Drum Acceptance Letter	App.1554
2024-10-28	Prince Lobel Strategic Rejection Letter	App.1555
2024-10-28	Robert Head (Hemp for Victory) Acceptance Letter	App.1556

DATE	DESCRIPTION	PAGE
2024-10-28	Sandra Rapke Rejection Letter	App.1557
2024-10-28	Shanetha Lewis Acceptance Letter	App.1558
2024-10-28	Smart Approaches to Marijuana Acceptance Letter	App.1559
2024-10-28	State of Nebraska Acceptance Letter	App.1560
2024-10-28	Synthcon LLC Rejection Letter	App.1561
2024-10-28	Tennessee Bureau of Investigation Acceptance Letter	App.1562
2024-10-28	Teresa Simon Rejection Letter	App.1563
2024-10-28	The Commonwealth Project Acceptance Letter	App.1564
2024-10-28	The Doc App Acceptance Letter	App.1565
2024-10-28	Victor Bohm (Hemp for Victory) Acceptance Letter	App.1566
2024-10-28	Village Farms International Inc. Acceptance Letter	App.1567
2024-10-28	Wei He Rejection Letter	App.1568
2024-11-25	American Psychological Association Rejection Letter	App.1569
2024-11-25	American Trade Association for Cannabis Rejection Letter	App.1570
2024-11-25	Americans for Safe Access Foundation Rejection Letter	App.1571
2024-11-25	Andrew DeAngelo Rejection Letter	App.1572
2024-11-25	Andrew Kline Rejection Letter	App.1573
2024-11-25	Ariana Fleishman Rejection Letter	App.1574
2024-11-25	Association of American Railroads Rejection Letter	App.1575

DATE	DESCRIPTION	PAGE
2024-11-25	Association of State Criminal Investigative Agencies Rejection Letter	App.1576
2024-11-25	August Wakat Rejection Letter	App.1577
2024-11-25	Brian Austin Rejection Letter	App.1578
2024-11-25	Bryan Krumm Rejection Letter	App.1579
2024-11-25	Bryon Adinoff Rejection Letter	App.1580
2024-11-25	Catherine Bloom Rejection Letter	App.1581
2024-11-25	Coalition for Patients Rights Rejection Letter	App.1582
2024-11-25	Con Body Rejection Letter	App.1583
2024-11-25	Cris Ericson Rejection Letter	App.1584
2024-11-25	Cynthia Mateo Rejection Letter	App.1585
2024-11-25	Daniel Kyle Rejection Letter	App.1586
2024-11-25	David Heldreth Jr. Rejection Letter	App.1587
2024-11-25	Dennis Schuller Rejection Letter	App.1588
2024-11-25	Derek J. Shirley Rejection Letter	App.1589
2024-11-25	Devan Maurice Dupuis Rejection Letter	App.1590
2024-11-25	Dominique Mendiola Rejection Letter	App.1591
2024-11-25	Drug Policy Alliance Rejection Letter	App.1592
2024-11-25	Ean Seeb Rejection Letter	App.1593
2024-11-25	Ed Wood Rejection Letter	App.1594
2024-11-25	Emily Fisher Rejection Letter	App.1595

DATE	DESCRIPTION	PAGE
2024-11-25	Grayson Lichtenthaler Rejection Letter	App.1596
2024-11-25	Greenspoon Marder, LLP Rejection Letter	App.1597
2024-11-25	Ian Patrick Patriarca Rejection Letter	App.1598
2024-11-25	Jasmine Montoya Rejection Letter	App.1599
2024-11-25	Jessica Garza Rejection Letter	App.1600
2024-11-25	Jonathan Frank Rejection Letter	App.1601
2024-11-25	Jordan Christopher Zito Rejection Letter	App.1602
2024-11-25	Jordan Smith Rejection Letter	App.1603
2024-11-25	Joseph Garofalo Rejection Letter	App.1604
2024-11-25	Joshua Taylor Rejection Letter	App.1605
2024-11-25	Julie Monteriro Rejection Letter	App.1606
2024-11-25	Justin J. Taylor Rejection Letter	App.1607
2024-11-25	Kai Hoffman Rejection Letter	App.1608
2024-11-25	Kainan Boring Rejection Letter	App.1609
2024-11-25	Keila E. Castillo Rejection Letter	App.1610
2024-11-25	Keith G. Freeman Rejection Letter	App.1611
2024-11-25	Kym Silva Rejection Letter	App.1612
2024-11-25	Last Prisoner Project Rejection Letter	App.1613
2024-11-25	Lilly Tirado Rejection Letter	App.1614
2024-11-25	Lori Robinson Rejection Letter	App.1615
2024-11-25	Major Cities Chiefs Association Rejection Letter	App.1616

DATE	DESCRIPTION	PAGE
2024-11-25	Major County Sheriffs of America Rejection Letter	App.1617
2024-11-25	Mariah Ashley Magnuson Rejection Letter	App.1618
2024-11-25	Marijuana Policy Project Rejection Letter	App.1619
2024-11-25	Michael Doyle Rejection Letter	App.1620
2024-11-25	Michael Krawitz Rejection Letter	App.1621
2024-11-25	Michael Rountree Rejection Letter	App.1622
2024-11-25	Minorities for Medical Marijuana, Inc. Rejection Letter	App.1623
2024-11-25	Minority Cannabis Business Association Rejection Letter	App.1624
2024-11-25	National Alliance of State Drug Enforcement Agencies Rejection Letter	App.1625
2024-11-25	National Association of Police Organizations Rejection Letter	App.1626
2024-11-25	National District Attorneys Association Rejection Letter	App.1627
2024-11-25	National HIDTA Directors Association Rejection Letter	App.1628
2024-11-25	National Narcotic Officers' Associations' Coalition Rejection Letter	App.1629
2024-11-25	National Organization for the Reform of Marijuana Laws (NORML) Rejection Letter	App.1630
2024-11-25	New York Office of Cannabis Management Rejection Letter	App.1631
2024-11-25	Nicholas Barreto Rejection Letter	App.1632

DATE	DESCRIPTION	PAGE
2024-11-25	Nicole Ricci Rejection Letter	App.1633
2024-11-25	Patrick Oglesby Rejection Letter	App.1634
2024-11-25	Perkins Coie Rejection Letter	App.1635
2024-11-25	Perkins Coie on behalf of Green Thumb Industries Inc. Rejection Letter	App.1636
2024-11-25	Perkins Coie on behalf of MedPharm Rejection Letter	App.1637
2024-11-25	Perkins Coie on behalf of MedPharm Rejection Letter	App.1638
2024-11-25	Perkins Coie on behalf of MedPharm Rejection Letter	App.1639
2024-11-25	Rafael Acevedo Rejection Letter	App.1640
2024-11-25	RTI International Rejection Letter	App.1641
2024-11-25	Russell Palmer Rejection Letter	App.1642
2024-11-25	Sage Endoom Cannablisshum Rejection Letter	App.1643
2024-11-25	San Diego County Rejection Letter	App.1644
2024-11-25	Sensible Drug Policy Rejection Letter	App.1645
2024-11-25	Sergeants Benevolent Association Rejection Letter	App.1646
2024-11-25	Shane Gallichio Rejection Letter	App.1647
2024-11-25	Shane Pennington Rejection Letter	App.1648
2024-11-25	State of Colorado Rejection Letter	App.1649
2024-11-25	Stephen J. Mandile Rejection Letter	App.1650
2024-11-25	Students for Sensible Drug Policy Rejection Letter	App.1651
2024-11-25	Suzanne Sisley, M.D. Rejection Letter	App.1652

DATE	DESCRIPTION	PAGE
2024-11-25	T. Christopher Wright Rejection Letter	App.1653
2024-11-25	The Equity Trade Network Rejection Letter	App.1654
2024-11-25	The Plant Counsel Rejection Letter	App.1655
2024-11-25	The Veterans Action Council Rejection Letter	App.1656
2024-11-25	Thomas J. Tobin Rejection Letter	App.1657
2024-11-25	Training Marbles, Inc. Rejection Letter	App.1658
2024-11-25	United Empowerment Party Rejection Letter	App.1659
2024-11-25	United States Cannabis Coalition Rejection Letter	App.1660
2024-11-25	Veterans Action Council Rejection Letter	App.1661
2024-11-25	Veterans Action Council Rejection Letter	App.1662
2024-11-25	Veterans Action Council Rejection Letter	App.1663
2024-11-25	Vicente LLP on behalf of Sensible Colorado Rejection Letter	App.1664
2024-11-25	Vicente LLP Rejection Letter	App.1665
	University of California San Diego's Center for Medicinal Cannabis Rejection Letter	App.1666
2024-11-27	Draft letters document listing by Heather E. Achbach	App.1667

Dated: February 17, 2025 Respectfully submitted,

/s/Austin T. Brumbaugh

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June 17, 2024

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Drug Enforcement Administration Attn: Hearing Clerk/OALJ 8701 Morrissette Drive Springfield, VA 2215

Re: Notice of Appearance

Dear Sir:

Please take notice that American Trade Association for Cannabis and Hemp ("ATACH") requests to appear in the matter of the Rescheduling of Marijuana, 89 Fed. Reg. 44,597 (the "Proposed Rule"), if DEA grants any other interested person's petition for a hearing.

- (A) ATACH has standing to participate in a hearing if one occurs. ATACH is an "interested person" and falls within the CSA's zone of interests. Further, ATACH and its members will be directly and "adversely affected" or "aggrieved" by the Proposed Rule if finalized. ATACH's status as an "interested person" is further detailed in the enclosed submission.
- (B) Among other things, ATACH has unique expertise and would provide invaluable insights into: (i) medical research involving marijuana, particularly as it relates to veterans' access; (ii) effects on members who are minority-owned and small businesses and whose communities have been impacted by the war on drugs; (iii) the impact of new marijuana-specific DEA controls on ATACH's members; (iv) abuse potential and public health risks of marijuana and (v) the practical consequences of rescheduling across the marijuana supply chain, from seed-to-sale. Further detail about the objections or issues on which ATACH desires to be heard is provided in the enclosed submission.
- (C) ATACH represents a coalition of active participants in and around the state-legal cannabis industry that are directly and adversely affected by the Proposed Rule. ATACH is thus uniquely situated to assist DEA's administrative decision making if DEA desires a hearing. ATACH and its members have extensive knowledge and experience regarding the practical effects of the Proposed Rule on the state-legal, regulated marijuana marketplace. DEA is actively seeking comments related to the practical consequences of rescheduling marijuana. Proposed Rule at 44,621. ATACH is particularly well-suited to provide this insight, as it represents a broad coalition of interests, including (but not limited to) distributors, seed-to-sale technology providers, economic consultants, ingredient and garden care suppliers, financial service providers serving the cannabis industry, non-profit researchers, and veterans groups, among

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Drug Enforcement Administration Attn: Hearing Clerk/OALJ June 17, 2024 Page 2

other voices. ATACH's positions with regard to the particular objections or issues are further detailed in the enclosed submission.

All notices to be sent pursuant to this appearance should be addressed to:

Abdul Kallon 1201 Third Ave., Ste. 4900 Seattle, WA 98101

Respectfully yours,

/s/ Abdul Kallon Abdul Kallon

AK:tjt

167742422.1

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June 17, 2024

Filed: 02/17/2025

BY FIRST-CLASS AND FEDEX MAIL

Drug Enforcement Administration, Attn: Administrator Hon. Anne Milgram
Docket No. DEA-1362
8701 Morrissette Drive,
Springfield, Virginia 22152

RE: Request for Hearing on the Proposed Rule Rescheduling Marijuana, Docket No. DEA-1362

Dear Administrator Milgram:

Smart Approaches to Marijuana (SAM) hereby requests a hearing on the Proposed Rule that would reschedule marijuana from Schedule I to Schedule III under the Controlled Substances Act. See 89 Fed. Reg. 44,597 (May 21, 2024), Docket No. DEA-1362 ("NPRM"). SAM is a bipartisan alliance of organizations and individuals dedicated to a health-first approach to marijuana policy. It is comprised of medical doctors, lawmakers, treatment providers, preventionists, teachers, law enforcement officers and others who seek a middle road between incarceration and legalization. SAM's mission is to equip policymakers with commonsense proposals, based in reputable science, to promote public health and decrease marijuana use and its consequences. SAM opposes the removal of cannabis from Schedule I.

SAM is an interested person who would be adversely affected or aggrieved by the agency's action if marijuana were rescheduled. See 21 C.F.R. §§ 1300.01(b), 1308.44. Moving marijuana to Schedule III will negatively affect SAM by reducing restrictions on access to marijuana and thereby requiring SAM to divert resources and expend additional funds on new and different lines of effort to protect those most at risk—including at-risk youth—from the harms produced by more ready access to this psycho-active substance. A sweeping change in the regulatory environment would require SAM to divert resources from its current advocacy and informational efforts and expend resources on entirely different projects. The NPRM also requests expert testimony that SAM is uniquely situated to coordinate and provide to the agency. SAM's interest in this proceeding is also directly analogous to the interests of other public interest and professional associations whose requests for a hearing on the record during past attempts to reschedule marijuana were granted. See, e.g., NORML v. DEA, 559 F.2d 735, 742 (D.C. Cir. 1977) (noting

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RE: Request for Hearing in Docket No. DEA-1362 June 17, 2024 Page 2

that "NORML and the American Public Health Association" successfully requested a hearing on rescheduling cannabis).¹

As the most significant relaxation of restrictions on a psychoactive substance in the history of the CSA, the Proposed Rule deserves full consideration through a hearing on the record. In the NPRM, DEA went out of its way to request "additional information" and "expert opinions" on a host of complex subjects. SAM requests a hearing to present evidence on the subjects identified by DEA, including but not limited to, the following:

- 1. Marijuana's actual or relative potential for abuse.—SAM believes that the assessment of marijuana's actual or relative potential for abuse in the Proposed Rule is flawed. At a hearing, SAM would present evidence bearing upon several points demonstrating that marijuana has a higher actual rate of abuse and higher potential for abuse than acknowledged in the analysis presented by HHS. Among other things, SAM would present evidence from the Drug Abuse Warning Network (DAWN) related to adverse outcomes from the use of marijuana; evidence from the National Survey on Drug Use and Health (NSDUH) bearing upon the development of substance use disorder among users of marijuana; and evidence from other relevant studies and data sets.
- 2. Marijuana's risk to public health.—The Proposed Rule, relying on HHS's analysis, asserts that marijuana presents a lower public health risk profile in comparison to "most other comparator drugs." 89 Fed. Reg. at 44,601. But HHS did not compare marijuana against all Schedule I drugs; rather, it compared marijuana to a limited, hand-picked list of other controlled and noncontrolled substances (e.g., heroin, alcohol, cocaine). HHS also omitted entirely any comparison with Schedule I hallucinogens. At a hearing, SAM would present evidence from expert witnesses to provide a more balanced analysis of the public health risks posed by marijuana.

The Proposed Rule also fails to consider research demonstrating that marijuana plays a causal role in the development of psychosis, including schizophrenia, in certain individuals. At the hearing, SAM would produce evidence concerning this link.

SAM respectfully notes that administrative law judges (ALJs) at DEA are almost certainly inferior officers under the Constitution. As a result, their appointment by the Administrator is inconsistent with the Appointments Clause of Article II. See, e.g., Lucia v. SEC, 585 U.S. 237 (2018). SAM raises this issue to make clear that, by requesting a hearing as permitted by 21 U.S.C. § 811(a) and 21 C.F.R. § 1308.44, SAM does not consent to a hearing before an ALJ who has not been appointed in a manner consistent with the requirements of the Appointments Clause, and SAM expressly preserves its right to challenge the outcome of any hearing on the ground that the ALJ was not properly appointed.

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RE: Request for Hearing in Docket No. DEA-1362 June 17, 2024 Page 3

Additionally, HHS elides the significant danger of marijuana-impaired driving by ignoring the *rate* of self-reported impaired driving by users of marijuana (which is far higher than the rate of impaired driving among users of other substances, including alcohol). At a hearing, SAM would provide evidence on this and related points.

The Proposed Rule also downplays the unique risks that marijuana poses to youth and adolescents. At a hearing, SAM would provide expert testimony showing that cannabis use harms adolescent brain development, diminishes learning, and inhibits mental processing speed. This evidence is critical because this aspect of the public health risks posed by marijuana appears to have been ignored by HHS.

SAM would also provide evidence related to the health risks of marijuana use during pregnancy.

3. The redefinition of "Currently Accepted Medical Use."—To change marijuana's designation as a Schedule I substance, HHS had to change the standard for determining "currently accepted medical use." The new test uses only two factors under which a substance has an accepted medical use, namely (i) if licensed healthcare providers have widespread current experience with medical use of the drug and (ii) if that medical use has "some credible scientific support." Memorandum for the Commissioner, FDA, from the Assistant Secretary for Health, HHS, Re: Part 1 Analysis at 1-2 (July 17, 2023) (HHS Memo). Under this new test, HHS concluded that marijuana has a currently accepted medical use for "anorexia related to a medical condition; nausea and vomiting (e.g., chemotherapy-induced), and pain." Id. at 29.

At a hearing, SAM would present testimony showing that marijuana does not satisfy the second factor of the new test because there is not credible scientific support that marijuana can be used to treat anorexia, chemotherapy-induced vomiting, or pain.

4. Marijuana's history or pattern of abuse.—HHS found that marijuana has a potential for abuse less than the drugs or other substances in schedules I and II, and the DEA requested additional evidence related to this point. See, e.g., 89 Fed. Reg. at 44,603 (requesting "additional data" on marijuana's actual or potential for abuse). At a hearing, SAM would present testimony showing that marijuana's history and pattern of abuse is much more like that of Schedule I substances than Schedule III substances.

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RE: Request for Hearing in Docket No. DEA-1362 June 17, 2024 Page 4

All notices to be sent pursuant to the proceeding should be addressed to:

Torridon Law PLLC Patrick F. Philbin 1155 F St. NW Suite 750 Washington D.C. 20004

Respectfully submitted,

Patrick F. Philbin

Counsel for Smart Approaches to Marijuana

CC: Hearing Clerk/OALJ
 DEA Federal Register Representative/DPW
 Drug Enforcement Administration
 8701 Morrissette Drive, Springfield, Virginia 22152.





















June 17, 2024

Drug Enforcement Administration, Attn: Administrator The Honorable Anne Milgram Docket No. DEA–1362 8701 Morrissette Drive, Springfield, Virginia 22152

RE: Request for Hearing on the Proposed Rule Rescheduling Marijuana, Docket No. DEA–1362

Dear Administrator Milgram,

The undersigned organizations hereby request a hearing on the Proposed Rule rescheduling marijuana from Schedule I to Schedule III. See 89 Fed. Reg. 44,597 (May 21, 2024), Docket No. DEA-1362.

Our organizations, representing diverse voices within the law enforcement community, have been intimately involved in the enforcement and implementation of our nation's drug laws and strategies. We understand the need for well thought out and rational policies that seek to keep our communities safe and healthy.

Given that marijuana has been classified as a Schedule I drug since 1970, it is imperative that any effort to move marijuana to another regulatory scheme should be given a formal hearing to provide it with a careful, unbiased review of the evidence during the rulemaking process. The science and the public health consequences of rescheduling should be the most important factors when making any decision given the long-term implications.

All notices to be sent pursuant to the proceeding should be addressed to:

Association of State Criminal Investigative Agencies C/O: Bureau of Criminal Investigation -Virginia State Police 7700 Midlothian Turnpike North Chesterfield, VA 23235

Drug Enforcement Association of Federal Narcotics Agents P.O. Box 2801 Ashburn, Virginia 20146.

National District Attorneys Association

National HIDTA Directors Association

National Narcotic Officers' Associations'

455 Massachusetts Avenue NW, Box 112

Sergeants Benevolent Association NYPD

C/O: Washington/Baltimore HIDTA

1800 Washington Blvd, Suite 150

1400 Crystal Drive, Suite 330

Arlington, VA 22202

Baltimore, MD 21230

Washington, DC 20001

57 Leonard Street New York, NY 10013

Coalition

Major Cities Chiefs Association PO Box 71690 Salt Lake City, UT 84171

Major County Sheriffs of America P.O. Box 81762 Rochester, MI 48308

National Alliance of State Drug Enforcement Agencies P.O. Box 16278 Austin, TX 78761

National Association of Police Organizations 317 S. Patrick Street Alexandria, VA 22314

Thank you for your consideration.

Sincerely,

Drew Evans

President, Association of State Criminal Investigative Agencies

Marshal Fisher

Marshall & Jisher

Negan & Voland

President, Drug Enforcement Association of Federal Narcotics Agents

Laura Cooper

Executive Director, Major Cities Chiefs Association

Megan Noland

Executive Director, Major County Sheriffs of America

mel f. They

Donald Payton

President, National Alliance of State Drug Enforcement Agencies

William J. Johnson, Esq.

Executive Director, National Association of Police Organizations

Nelson O. Burn. Jr

Nelson Bunn

Executive Director, National District Attorneys Association

Mike McDaniel

Eic Brown

J. Me Mil

President, National HIDTA Directors Association

Fric Brown

President, National Narcotic Officers' Associations' Coalition

Vincent J. Vallelong

President, Sergeants Benevolent Association NYPD

cc: Hearing Clerk/OALJ

DEA Federal Register Representative/DPW

Drug Enforcement Administration

8701 Morrissette Drive Springfield, Virginia 22152.



Association of Federal Narcotics Agents www.afna.org

Honorable Ann Milgram Administrator U.S Drug Enforcement Administration 8701 Morrissette Drive, Springfield, Virginia 22152 June 18, 2024

RE: Request for Hearing Period on the Proposed Rule Rescheduling Marijuana, Docket No. DEA-1362

Dear Administrator Milgram,

As President of DEAFNA and on behalf of our organization, I respectfully request a hearing on the Proposed Rule announced on May 21, 2024 that would reschedule marijuana from Schedule 1 to Schedule III under the Controlled Substances Act (CSA).

I have attached a copy of DEAFNA'S letter to you dated May 6, 2024, indicating our opposition to rescheduling. Additionally, I have attached a position paper authored by two of our members.

As stated in our letter recent communication from the Assistant Secretary for Health and Human Services (HHS) in support of rescheduling marijuana is unfounded and in direct contradiction with its own SAMSHSA (Substance Abuse and Mental Health Services Administration) evidence-based literature, NSDUH (National Survey on Drug Use and Health) reports, and grantee marijuana attestation requirements.

We are currently in the throes of the deadliest drug threat in the history of America with respect to the fentanyl crisis. Consideration of such a drastic negative and permanent impact on our nation at this time is at best bad timing, reckless and completely disregards current science.

The first duty of government is to protect our citizens. This is a public safety and public health issue that deserves a formal hearing. Thank you for your commitment to Drug Enforcement and for your kind consideration of our request.

Sincerely

Marshall Fisher

President

Drug Enforcement Association of Federal Narcotics Agents

Marshallfisher@rocketmail.com

601-832-8449

www.afna.org

David G. Evans, Esq.

Senior Counsel
Cannabis Industry Victims Educating Litigators
203 Main St. # 149
Flemington, NJ 08822
908-963-0254
seniorcounsel@CIVEL.org

June 18, 2024

Drug Enforcement Administration Attn: Hearing Clerk/OALJ 8701 Morrissette Drive Springfield, Virginia 22152

Drug Enforcement Administration Attn: DEA Federal Register Representative/DPW 8701 Morrissette Drive Springfield, Virginia 22152.

Subject: Request for Hearing on Docket No. DEA-1362

Dear Sir/Madam:

The undersigned David G. Evans hereby requests a hearing in the matter of: Docket No. DEA-1362 the rescheduling of marijuana.

Cannabis Industry Victims Educating Litigators (CIVEL) educates litigators and legislators nationally on how to protect the many victims of the marijuana industry. The categories of the victims of the marijuana industry that CIVEL seeks to protect include:

Accident victims.

Abused elders

Unborn children and nursing babies

Children of marijuana users

Crime victims

Domestic violence victims

Drug Dealer Liability Act victims

Employers

Environmental victims

Parents and grandparents

Marijuana consumers

Marijuana addicts

Marijuana intoxicated driving victims

People who suffer mental health impairment due to marijuana

Property owners
Sexual victims
Students and schools
Workers and farm employees in the marijuana industry

Mr. Evans will testify on the following issues:

- 1. Section 280E of the Internal Revenue Code
- 2. There Is No Reason to Change Marijuana's Scheduling Based on the Science or Law
- 3. Marijuana Exposures Among Children, Veterans With PTSD, Older Adults
- 4. Deadly Interactions Between Marijuana and Prescription Drugs
- 5. Marijuana Use Causes Mental Illness and Violence
- 6. CBD as a "Medicine" the Wild Claims
- 7. Today's Marijuana Is Very High in Potency and Causes Public Health and Safety Harms and Addiction
 - 8. The Department of Justice States That Marijuana Users Are Dangerous
- Marijuana Use Before, During or after Pregnancy Can Cause Serious Medical Conditions, Learning Problems, and Birth Defects

All notices to be sent pursuant to the proceeding should be addressed to:

David G. Evans, Esq. 1854 Hendersonville Rd Ste 205 Asheville, NC 28803 thinkon908@aol.com

Respectfully yours,

David G. Evans

Page 32 of 214



Coalition for Patient Rights: Administration

Filed: 02/17/2025

Post Office Box 750865 LAS VEGAS, NV 89136

www.COALITIONFORPATIENTRIGHTS.org

June 18, 2024

To: Drug Enforcement Administration

Attn: Administrator,

Hearing Clerk/OALJ, and

DEA Federal Register Representative/DPW

8701 Morrissette Drive Springfield, Virginia 22152

Subject: Request for Hearing for Docket No. DEA-1362

Dear Sir:

The undersigned hereby requests a hearing in the matter of: Docket No. DEA-1362

Coalition For Patient Rights (CPR): Jeff Krajnack - CPR President and Tom Lauerman "Farmer Tom" CPR Board of Directors and Director of Patient Safety MyCPR.us

Compassion Center (CC): Jason Greninger - CPR/CC Legislative & Congressional Outreach Coordinator Compassion-Center.org

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Community-Based Clinical Cannabis Evaluation & Research Network (CBCCERN) and Center For Incubation and Findings (CIFR): James Creel - Executive Administrator CBCCERN.org & CIFR.cc

Integrative Providers Association (IPA): Julie Monteiro RN, BSK- President and Director of Education IntegrativeProviders.org

Decriminalize Nature (DN): James Garvey - Co-Director and Treasurer and Jennifer Gullickson - Co-Director DecrimNatureNV.org

CPR Introduction:

The Coalition for Patient Rights (CPR) is committed to advancing the rights of all patients in the pursuit of accessing safe and effective medical cannabis treatments. In light of ongoing debates surrounding the federal regulation of cannabis, CPR has carefully considered the implications of both decriminalization and rescheduling on many levels, especially in relation to patient and civil rights. From the heartbeat of our patients,

CPR finds that Decriminalization and Descheduling best serves the needs of our patients, community and the underserved.

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Coalition for Patient Rights: Administration

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This position was based on current empirical data, that cannabis has been used safely throughout history for centuries and that it existed and was legal prior to the creation of both the FDA & DEA, in which cannabis should never have been placed on the schedule to begin with. In addition, the majority of states, through a patchwork of current state laws, are 'in favor' of its medical or adult use, in multiple forms deemed legal as a safe treatment option that has been beneficial and part of millions of patient's treatment plans. Cannabis is in need to be descheduled and decriminalized so that this simple plant can be treated as such.

1. Interest in the proceeding:

Our interest in this proceeding is driven by our dedication to advocating for the responsible use of natural substances, ensuring that regulatory measures reflect current scientific understanding, and promoting public health and safety. Our collaboration with other organizations amplifies the collective concern and interest in re-evaluating current scheduling practices.

2. Objections or issues to be heard:

We collectively wish to address several critical objections and issues in this proceeding:

- Scientific Evidence: The scheduling under Schedules III may not accurately reflect the risk profiles and therapeutic benefits.
- Public Health and Safety: The socio-economic and public health impacts of criminalizing these substances, including the burden on the legal system, the stigmatization of users, and the adverse effects on community health, need thorough examination.
- Harm Reduction: We advocate for policies that prioritize harm reduction, education, and informed consent over punitive measures. Evidence-based approaches can better serve public health interests.

3. Position Regarding the Objections or Issues:

Our position is that the scheduling of substances should be evaluated based on contemporary scientific research and peer reviewed world wide public health data. We propose a decriminalization approach that:

- Provides non-restrictive, full access to treatments.
- Is less cost impactive to the patient and to the current healthcare system

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- Removes Legal Penalties: Minimizes unnecessary legal penalties that disproportionately affect marginalized communities.
- Promotes Education and Safety: Emphasizes public education on the safe use and harm reduction strategies.

We respectfully request the opportunity to present our case and provide evidence supporting our position during the hearing. We believe that a thorough, science-based review is essential for fair and effective regulatory policies. Our organization, along with our collaborators, is prepared to contribute detailed research, expert testimony, and community impact statements to inform this proceeding.

Thank you for considering our request. We look forward to your response and the opportunity to participate in this important review process.

Respectfully yours,

/s/ Jason Greninger CPR Legislative & Congressional Outreach Coordinator











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Coalition for Patient Rights: Administration

Filed: 02/17/2025

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POSITION STATEMENT: Decriminalization vs. Descheduling of Cannabis

Section I: Introduction

The Coalition for Patient Rights (CPR) is committed to advancing the rights of all patients in the pursuit of accessing safe and effective medical cannabis treatments. In light of ongoing debates surrounding the federal regulation of cannabis, CPR has carefully considered the implications of both decriminalization and rescheduling on many levels, especially in relation to patient and civil rights. From the heartbeat of our patients,

CPR finds that Decriminalization and Descheduling best serves the needs of our patients, community and the underserved.

This position was based on current empirical data, that cannabis has been used safely throughout history for centuries and that it existed and was legal prior to the creation of both the FDA & DEA, in which cannabis should never have been placed on the schedule to begin with. In addition, the majority of states, through a patchwork of current state laws, are 'in favor' of its medical or adult use, in multiple forms deemed legal as a safe treatment option that has been beneficial and part of millions of patient's treatment plans. Cannabis is in need to be descheduled and decriminalized so that this simple plant can be treated as such.

Section II: Definitions

Unless the context requires otherwise, the following definitions shall apply:

(a) "Medicinal Cannabis" and/or "Medical Marijuana" and/or "Medical Cannabis" means any such form of cannabis or a cannabis product used in compliance with state laws, and marijuana is to be properly addressed as "Medicinal Cannabis" when referring to its medicinal use, qualities and/or beneficial compounds used in the treatment of any illness and/or medical condition and/or relieving pain not well addressed by existing FDA approved remedies and/or treatment options.



- (b) "Decriminalization" refers to the elimination or reduction of criminal penalties associated with the possession or use of cannabis, often resulting in civil fines or alternative measures rather than criminal charges.
- (c) "Rescheduling" means rescheduling of marijuana (cannabis) in the U.S. DEA Drug Scheduling would involve the reclassification of cannabis under the Controlled Substances Act (CSA), typically shifting it from its current Schedule I status to a lower schedule, such as Schedule II, III, or VI.
- (d) "Descheduling" refers to the process of eliminating the marijuana (cannabis) plant from a long list of controlled substances outlined in the Controlled Substances Act of 1970 (CSA) and any subsequent legislative measures derived from or associated with this original law. In essence, descheduling entails removing the legal classification of marijuana as a controlled substance, thereby altering its regulatory status and potentially allowing for different legal frameworks on a state-level regarding its production, distribution, possession and/or use. This action would signify a significant shift in drug policy, potentially leading to changes in how the marijuana (cannabis) plant is being regulated and perceived within the legal system.
- (e) "Schedule VI" refers to states and governments who have added a new schedule, Schedule VI, to their Controlled Substances Act (CSA), which legally categorizes the Cannabis plant(s) and tetrahydrocannabinol (THC) below other related substances that have a low(er) potential for abuse relative to substances listed in Schedules I, II, III, IV and V and have currently accepted medical uses in the United States. Substances in a CSA Schedule VI also have a lower risk of dependence and/or addiction compared to those in the Schedules I through V. Examples of some of the substances included in CSA Schedule VI are marijuana and tetrahydrocannabinol that is not derived from hemp, and only in a growing body of states like Virginia and North Carolina. These substances are subject to regulations regarding the growing, manufacturing, distribution, prescription, and use to prevent abuse and diversion, but are still a Schedule VI.
- (f) "GRAS Designation" is defined as "Generally Recognized as Safe", a designation granted by the Food and Drug Administration (FDA) for substances having been adequately shown to be safe under the conditions of its intended use and considered safe for human consumption based on scientific evidence. Food products are classified as GRAS, and under this designation may enhance product safety and quality assurance, providing consumers and cannabis patients with assurances of standardized potency and purity.
- (g) "Section 280E" refers to the Internal Revenue Code that is currently prohibiting legal cannabis businesses from deducting ordinary business expenses from their federal taxes, resulting in significant financial burdens. Rescheduling or Descheduling cannabis could alleviate these tax burdens, enabling businesses to reinvest in research, development, and patient care initiatives.

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Section III: Considerations

Several key arguments based on the legal principles, public policy considerations and many other practical implications support descheduling cannabis altogether as opposed to just rescheduling it. The following considerations were made:

Constitutional considerations: The Controlled Substances Act (CSA) is a federal regulatory framework that affects interstate commerce, individual liberties, and states' rights, as well as scheduling the controlled substances for identification and regulation. Cannabis is completely freed from the CSA's purview by descheduling, ending federal prohibition and reestablishing individual and states' rights to regulate accordingly.

State Sovereignty and Federalism: The CSA framework does not fully respect states' rights and sovereignty when cannabis is moved to a lower schedule, it just perpetuates the ongoing contradictions. Conflicts between state and federal law are perpetuated by states that have decided to legalize cannabis for medical or recreational uses. States would be able to regulate cannabis as they see fit without interference from the federal government if it were descheduled.

Public Health and Access to Medicine: If cannabis is rescheduled, significant regulatory barriers may still be present, making it more difficult for patients in need or for researchers to conduct research and obtain medical cannabis for legitimate purposes. These obstacles are removed when cannabis is descheduled, allowing for more extensive research, development, and access to cannabis-based medications for patients.

Current Status Marginalization and Racial Disparities: Cannabis' current Schedule I status has had a disproportionately negative impact on marginalized communities, resulting in mass incarcerations and the continuation of racial disparities in the criminal justice system. Placing cannabis into yet another schedule will not solve the marginalization and racial disparities, the legal recreational market will continue profiting making billions of dollars while the incarcerated sit idol- unjustly awaiting their release. Descheduling cannabis promotes social justice and equity while acknowledging the War on Drugs' failure and allowing the acquittal of prior cannabis-related convictions.

Financial Opportunities and Business Development: Federal banking laws, regulations, financing difficulties, and ongoing tax issues will also impact the cannabis industry if the industry is rescheduled. Access to regular banking solutions, investment opportunities, and interstate business are all made possible by the descheduling of cannabis, which also promotes business growth and career development.

International Consequences: It may be difficult to implement global drug policy if the cannabis plant remains to be rescheduled within the CSA framework, in violation of several international drug treaties and conventions. The United States would be leading the way in reforming foreign substance treaties by advancing proof-based drug policies worldwide, descheduling cannabis.

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Section	VI: C	ontic	ns

Decriminalization: Decriminalization would also remove federal restrictions, allowing for broader research (opening it up beyond universities), development, and free distribution of other medical cannabis products without incrimination. This would enhance patient access to diverse treatment options, eliminate the drive for black market products and facilitate innovation in medical cannabis therapies. Most importantly, it would reduce the risk of legal consequences for the patients using cannabis for medical purposes and would be less likely to incriminate patients with archaic DUID laws that are only based on speculation.

In addition, cannabis regulations may not currently address the regulatory challenges related to product safety, quality control, and standardized dosing, potentially impacting patient safety and efficacy. Current access to cannabis now provides risks both in the legal and illicit markets for the patient populations. Decriminalization would allow those current state laws to continue as their constituents voted in to be, providing ease of access to consumers. Imagine the ability to buy 'hemp' sprouts at the local grocers and/or farmers' markets next to the alfalfa sprouts and tomatoes. Ultimately, this option would "Free the Leaf" once and for all.

Rescheduling: Rescheduling cannabis to Schedule III, IV or V, or creating a new Schedule VI could facilitate research and development of medical cannabis products, leading to improved patient access and safer products. However, restrictive regulations and barriers to access may persist, limiting patient autonomy and choice in addition to creating monopolies for those in power to set up regulations that benefit only those at the state and federal level, causing further division in equity and access.

GRAS Designation: GRAS designation of marijuana (cannabis) could enhance product safety and quality assurance, providing patients with assurances of standardized potency and purity.

Section V: Challenges and Questions

Despite the potential benefits of descheduling, several challenges and unanswered questions remain:

Research Gaps: What additional research is needed to fully understand the medical benefits and risks of cannabis?

Regulatory Framework: How can regulatory frameworks be established to ensure product safety and quality control, while leading towards consistency and standardized dosing?

Healthcare Integration: How can medical cannabis be integrated into mainstream healthcare practices to ensure comprehensive patient care?

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Equity and Access: How can disparities in access to medical cannabis treatment be addressed, particularly among marginalized communities?

Section VI: Facts

Polls consistently show that a clear majority of the public now supports marijuana legalization. For example, a Pew Research Center poll released in November 2022 found that approximately 88% (percent) of Americans agreed that marijuana should be legal for medical or recreational use, with nearly 60 percent supporting legalization for both medical and recreational use. A majority of our medical professionals accept the medical use of marijuana and support removing marijuana from schedule I, so what are we waiting on as an organized society formed in service to the people?

In a letter from 12 senators to our U.S. attorney general and to the U.S. DEA, it was stressed that "88% percent of Americans are now in support of legalizing marijuana"*, and that any continued placement within the CSA "would not resolve the worst harms of the current system". Thus, the DEA should deschedule marijuana altogether. Marijuana's placement in the CSA has had a devastating impact on our communities and is increasingly out of step with state law and public opinion. We thank these Senators for reiterating that our patients should be properly served and empowered without criminal categories for cannabis.

The World Health Organization (WHO), the American Academy of Family Physicians (AAFP) and the American Nurses Association (ANA) have all recognized the legitimate medical uses of the cannabis plant (marijuana). The United States can persuasively argue that the decriminalization of marijuana is activity consistent with its treaty obligations of the "Single Convention on Narcotic Drugs of 1961" and that descheduling makes sense given the current research and knowledge.

Research has found that marijuana legalization may reduce violent international drug trafficking. By definition, the criminalization of cannabis will continue until it is completely removed from the CSA, and so the World Health Organization finds that patients and communities around the world are best served by decriminalization and descheduling given the potential legal ramifications.

Filed: 02/17/2025

Alcohol is not on the CSA, though many treatments and drugs contain alcohol. According to a statement made in congress, there were 140 thousand alcohol related deaths in 2022, and there were 500 deaths from tylenol, Cannabis had zero lethality reported. Now, we cannot pretend it is zero, as cannabis can be lethal if it contradicts treatment, but accidents from impairment are hard to track. With that; empirical data still indicates fruits or vegetables kill more people per year than the cannabis plant. This data shouts out to anyone who might still be confused, that cannabis is generally regarded as safe, and therefore should be classified as GRAS, but not scheduled at all.

If cannabis were in Schedule III, sharing joints would become as criminal as sharing ketamine or codeine. Decriminalization and descheduling of the cannabis plant creates a socially positive impact on patients, veterans, communities, and the underserved, without which, for them to receive a gift of cannabis is two crimes. This further weaponizes a legal system and a plant meant to improve lives.

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Archeology has proven that cannabis sativa has been a top choice for animal feed for over 2000 years. In the past it has been demanded by our government, even subsidized. For generations before prohibition, we received cannabinoids in our dairy and meat. From this we can conclude that for those generations, we viewed the cannabis sativa plant as GRAS.

All Mammals have an endogenous cannabinoid system (ECS) that manages and balances their homeostasis and other body systems. Since our bodies naturally manufacture two (2) of these endogenous cannabinoids, Anandamide (AEA) and 2-Arachidonoylglycerol (2-AG), they act as keys that interact with our locks, or receptors, on our cells and organs. The cannabis sativa plant has over 144 known phyto-cannabinoids that mimic our endogenous cannabinoids and each of their functionalities. While there are other plants in the Cannabaceae that contain cannabinoids, no other plant is known to have as much symbiosis with our cellular equilibriums as the Cannabis Sativa plant. Equilibriums controlling appetite, sleep, depression, anxiety, inflammation, and pain. Based on these connections with our endogenous cannabinoid system, taking into account peer reviewed research of known mechanisms of action for cannabinoids regarding healing, CPR feels that decriminalization and descheduling of Cannabis Sativa for our animal and food sources may be beneficial to our health; a benefit for the entire community, improving wellness, strengthening the community as a whole, thus creating less health interventions, unnecessary burden and costs.

Minus one demonized molecule, cannabis becomes hemp, and is currently sold throughout much of the US, because it is considered (without designation) GRAS. Search "hemp" at Amazon.com for proof: See for yourself. We represent that our patients are not criminals - for seeking relief. On August 7, 1765, George Washington noted that he "began to separate the male from the female hemp... rather too late." Female cannabis sativa flowers are for smoking and medicine, not rope.

Do you get the impression that George Washington regarded Cannabis female flowers to be GRAS, perhaps even medicinal, and that he was not committing a criminal act?

Conclusion:

In conclusion, arguing in favor of descheduling cannabis over re-rescheduling makes a strong case based on social justice, economic opportunities, international drug policy reform, states' rights, constitutional principles, and public health considerations. Cannabis regulation at the federal and international levels can now be more equitable, just, and sustainable thanks to a robust framework descheduling the cannabis plant, which also eliminates federal prohibition.

The Coalition for Patient Rights (CPR) advocates for a patient-centered approach to (medical) cannabis policy reform that prioritizes safe access, product safety, and even patient autonomy. While both decriminalization and rescheduling may offer incremental improvements, descheduling offers the most promising pathway to advancing patient rights and improving healthcare outcomes as a result. CPR calls for continued dialogue and collaboration to address the complex challenges and opportunities surrounding medical cannabis regulation, however, leans toward descheduling.

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Sources:

- Pew Research Center, "Americans Overwhelmingly Say Marijuana Should Be Legal For Medical or Recreational Use," Ted Van Green, November 22, 2022,
 - https://www.pewresearch.org/short-reads/2022/11/22/americans-overwhelmingly-say-marijuana-should-be-legal-for-medical-or-recreational-use/
- Bloomberg Law, "Moving Marijuana to Schedule III Would Aid Access to Legal Care," Andrew Kline and Shane Pennington, October 25, 2023, 21 U.S.C. 841, 844
 - https://news.bloomberglaw.com/us-law-week/moving-marijuana-to-schedule-iri-would-aid-access-to-legal-care
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- Economic Journal, "Is Legal Pot Crippling Mexican Drug Trafficking Organizations? The Effect of Medical Marijuana Laws on US Crime," Evelina Gavrilova, Takuma Kamada and Floris Zoutman, November 16, 2017, https://doi.org/10.1111/ecoj.12521; Center for American Progress, "Rethinking Federal Marijuana Policy," Ed Chung, Maritza Perez and Lea Hunter, May 1, 2018.
 - nttps://www.americanprogress.org/article-rethinking-federal-marijuana-policy
- 6. "Debate Over Rescheduling vs. De-Scheduling Cannabis"

USCA Case #24-1365 Document #2100970 Filed: 02/17/2025 Page 47 of 214

https://cofclv.org/debate-over-rescheduling-vs-de-scheduling-cannabis/

7. Controlled Substances Act (CSA)

https://www.dea.gov/drug-information/csa# ~ text=The%20Controlled%20Substances%20Act%20

- 8. Food and Drug Administration (FDA) https://www.fda.gov/
- 9. Drug Enforcement Act (DEA) https://www.dea.gov/drug-information/
- 10. Internal Revenue Code Section 280E
- 11. Schedule 6 Foundation.A simple and elegant political solution for American Cannabis.https://schedule6.org/

Coalition for Patient Rights (CPR) VOX POPULI: A Voice for The People

www.CoalitionforPatientRights.org

FB: Coalition For Patient Rights
FB Group: Coalition For Patient Rights

Twitter: @CPROrganization

Email: coalition@coalitionforPatientRights.org

President: Jeff.Krajnak@mycpr.us CPR Toll Free: (844)842-8687

About CPR: National Voice of Patient Advocacy

Coalition for Patient Rights provides a voice for the people, Vox Populi, aiming to improve the healthcare of the Nation by highlighting system failures, lobbying and advocating for regulatory change, treatment education, environmentally friendly policies, and safeguarding new technology.

MSOplus: Coalition For Patient Rights Administration - P.O. Box 750865, Las Vegas, NV 89136

WWW.COALITIONFORPATIENTRIGHTS.org a 501(c)4 Social Welfare Organization WWW.MyCPR.us

Standing up for Patient Rights in Legislative and Congressional Forums When The Voice of Industry Gets Too Loud! 7



U.S. DEA DRUG SCHEDULING

Schedule	Definition	Examples
	Brugs, substances, or diemicals are defined as drugs with no currently accepted medical use and a high potential for abuse	
Y	Drugs, substances, or Chemicals are defined as drugs with lower potential for abuse than Schedule IV and consist of preparations containing limited quantities of certain narcotics. Schedule V drugs are generally used for antidiarrheal, antitussive, and analgesic purposes.	

Position Statement Submitted to:

Cannabis Compliance Board | Zoom Meeting: 02/09/2024 at 1PM (PST) Comments by the public may be emailed to CACmeetings@ccb.nv.gov by 5:00 p.m. the day before the scheduled meeting and include the commenter's full name. Content may be redacted due to inappropriate language. All written public comments shall, in their entirety, be included as part of the public record.

MSOplus: Coalition For Patient Rights Administration - P.O. Box 750865, Las Vegas, NV 89136

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Standing up for Patient Rights in Legislative and Congressional Forums When The Voice of Industry Gets Too Loud! 8

6/19/24

To: Drug Enforcement Administration, Attn: Hearing Clerk/OALJ 8701 Morrissette Drive, Springfield, VA 22152

From: Rev. Bryan A. Krumm, CNP 733 Monroe St. NE Albuquerque, NM 87110 (505) 414-8120

Re: Request for Hearing

Pursuant to 21 CFR § 1316.47: I, Rev. Bryan Krumm, CNP, hereby request a hearing in the matter of: [Docket No. DEA-1362; A.G. Order No. 5931-2024]

Schedules of Controlled Substances: Rescheduling of Marijuana

On December 8, 2020, I filed a Rescheduling Petition for Cannabis with the DEA, requesting that Cannabis be removed from Schedule 1 of the Controlled Substances Act. This was 6 days after Cannabis had been removed from the most restrictive status of the Single Convention Treaty. Because I never received a response from the DEA, I re-filed the petition with the current administration on July 14, 2021. DEA acknowledged receipt of the petition on July 21, 2021 and stated "your petition is currently under review". After waiting for over a year, I sent a letter requesting the status of my rescheduling petition and on September 23,

2022 DEA responded to me claiming that they they must first request a review by the FDA before acting on my rescheduling petition.

Because the DEA has a long history of unreasonable delays regarding rescheduling petitions, I filed a complaint with the Court of Appeals for the DC Circuit, asking the court to intervene in order to protect the health, safety and welfare of American Citizens. Unfortunately my complaint was dismissed because I filed more than 30 days after DEA's response. I was forced to wait for the FDA to complete a review that should have begun nearly 2 years earlier. Fortunately, on October 6, 2022, President Joseph Biden released a statement asking the Secretary of Health and Attorney General an expedited review of how Cannabis was scheduled under federal law, and on August 29, 2023 HHS officially notified DEA that Cannabis should be moved to Schedule 3 of the CSA.

When it became clear that DEA was again delaying action these rescheduling petitions, even after FDA and HHS recommended that Cannabis be moved to Schedule 3, on February 2, 2024 I filed a petition for Writ of Mandamus asking the Court of Appeals to order DEA to fulfill it's legal obligation to reschedule Cannabis. Although the Court denied my request April 19, 2024, on April 30, 2024 the DEA announced that the Attorney General had ordered them to move Cannabis to Schedule 3 of the CSA.

This is not my first experience with DEA's use of delay as a tactic to prevent access to Medical Cannabis. On December 17, 2009, I filed a rescheduling petition requesting that Cannabis be removed from control under the Controlled Substances Act and that control of Cannabis be placed under control of the States. After nearly 7 years of delay, on August 12, 2016, the DEA that petition (Federal Register/Vol. 81, No. 156/Friday, August 12, 2016/Proposed Rules 53767 - 53844). DEA has still not fully complied with the recommendations from HHS from that petition.

For decades the DEA has blocked the Medical Cannabis research they require in order to demonstrate "accepted medical use in the United States". Evidence of the ongoing efforts by the DEA to prevent relevant Medical Cannabis research is found in the DEA's own "Denial of Petition to Initiate Proceedings to Reschedule Marijuana". The FDA admitted that "notably, it is beyond the scope of this review to determine whether these data demonstrate that marijuana has a currently accepted medical use in the United States" However, The FDA did report that the eleven studies evaluated in their review showed positive signals that marijuana may produce a desirable therapeutic outcome and has been shown to help chronic neuropathic pain, increase appetite in HIV, reduce spasticity in Multiple Sclerosis, produce bronchodilation in asthma, and reduce intraoccular

pressure in glaucoma. (Federal Register/Vol. 81, No. 156/Friday, August 12, 2016, 53792).

In his May 20, 2015 letter titled FDA Recommendations On The Scheduling Of Marijuana Under The Controlled Substances Act, to Karen DeSalvo (Acting Assistant Secretary for Health), Stephen Ostroff (Acting Commissioner of Food and Drugs) discussed 5 distinct areas of the federal regulatory system that have blocked efficient and scientifically rigorous research with marijuana and its constituents.

- 1. DEA has refused registration of additional cultivators of Cannabis for research.
- 2. PHS review is required for Cannabis research but not for other Schedule 1 substances.
- 3. DEA review of all research with Schedule 1 substances and registration requirements restrict research.
- 4. Certain Cannabis constituents have never been properly evaluated by HHS to determine if they should remain in Schedule 1.
- 5. DOJ/DEA and HHS need to reassess the legal and regulatory framework as applied to 1) assessment of abuse liability and 2) the assessment of currently accepted medical use for drugs that have not been approved by the FDA.

Karen DeSalvo further substantiated the futility of the administrative process in her June 3, 2015 letter to Chuck Rosenberg, when she stated "Concerns have been raised about whether the existing federal regulatory system is flexible enough to respond to increased interest in research into the potential therapeutic uses of marijuana and marijuana derived drugs." (Federal Register/Vol. 81, No. 156/Friday, August 12, 2016/Proposed Rules, 53768)

On December 2, 2020, the United States recommended that Cannabis be removed from the most restrictive status of the Single Convention Treaty and stated that Cannabis has proven medical value, declaring that "the legitimate use of a Cannabis preparation has been established through scientific research, and Cannabis no longer meets the criterion for placement in Schedule IV of the Single Convention". (Commission on Narcotic Drugs Reconvened sixty-third session Vienna, 2–4 December 2020. Statements following the voting on the WHO scheduling recommendations on cannabis and cannabis-related substances, p12)

The DEA has noted that Section 811 (d)(1) provides that where a drug is subject to control under the Single Convention, the DEA administrator (by delegation from the Attorney General) must "issue an order controlling such drug under the schedule he deems most appropriate to carry out such treaty obligations,

without regard to the findings required by [21 U.S.C. 811 (a) or 812 (b)] and without regard to the procedures prescribed by [21 U.S.C 811 (a) and (b)]......DEA need not consider the findings of sections 811(a) or 812(b) that have no bearing on that final determination, and DEA likewise need not follow the procedures prescribed by sections 811(a) and (b) with respect to such irrelevant findings" Federal Register/Vol. 81, No. 156/ Friday, August 12, 2016, Page 53767-53768.

Therefore, based the medical and scientific findings of the FDA, the DEA is required to at least move Cannabis to a schedule 3 of the CSA. However, medical and scientific findings of the FDA are not required to determine that Cannabis should be removed from control under the CSA and regulated like alcohol and tobacco, in order to protect the health, safety and welfare of the American People. The safety of Cannabis was previously considered by the DEA. "In The Matter of Marijuana Rescheduling", DEA Docket No. 86-22, September 6, 1988, resulted in a finding that, "Marijuana, in its natural form, is one of the safest therapeutically active substances known to man." Id. at pages 58-59. "The evidence in this record clearly shows that marijuana has been accepted as capable of relieving the distress of great numbers of very ill people, and doing so with safety under medical supervision. It would be unreasonable, arbitrary, and capricious for the DEA to

continue to stand between those sufferers and the benefits of this substance in light of the evidence in this record." Id. At page 68

In comprehensive reviews conducted by the Federal Government on the use of smoked Cannabis, experts have consistently concluded that smoked Cannabis is safe and effective for medical use. "The evidence is perfectly clear that smoking is an outstanding route of administration....it's a very safe drug and therefore it would be perfectly safe medically to let the patient determine their own dose through the smoking route". See National Institutes of Health. Transcript of the NIH Workshop on the Medical Utility of Marijuana. Tab B, Deliberations of the Ad Hoc Group of Experts; February 19&20, 1997. (Ace-Federal Reporters, Inc., Cr66002.0) See also Joy, Janet E., Stanley J., Watson, and John A. Benson, Jr., (eds) Marijuana as Medicine: Assessing the Science Base,. (National Academy Press 1999). "Until a nonsmoked rapid-onset cannabinoid drug delivery system becomes available, we acknowledge that there is no clear alternative for people suffering from chronic conditions that might be relieved by smoking marijuana, such as pain or AIDS wasting".

Under the CSA, the Attorney General has the authority to reschedule a drug if he finds that it does not meet the criteria for the schedule to which it has been assigned. 21 U.S.C. 811(a) 16 (2); see also Alliance for Cannabis Therapeutics v.

DEA, 15 F.3d 1131, 1133 (D.C. Cir.1994); Kuromiya v. United States, 37 F.Supp.2d 717,722 (E.D. Pa.1999) ("There are provisions by which the Attorney General may change the designation of a particular controlled substance, either to move it up, down, or off of the schedules.") (citing 21 U.S.C. 811). The Attorney General has delegated this authority to the Administrator of the DEA ("Administrator"). See Alliance for Cannabis Therapeutics, 15 F.3d at 1133.

Cannabis is an ancient drug, not a new drug. It has been safely used as a medication for thousands of years and there has never been a death due to any toxic effects. Comprehensive study of legal medical Cannabis users in the Federal IND found only mild changes in pulmonary function associated with long term heavy use. No functionally significant attributable sequelae were noted in any other physiological system examined in the study, which included: MRI scans of the brain, pulmonary function tests, chest X-ray, neuropsychological tests, hormone and immunological assays, electroencephalography, P300 testing, history, and neurological clinical examination. (Russo et.al. 2002, "Chronic Cannabis Use in the Compassionate Investigational New Drug Program: An Examination of Benefits and Adverse Effects of Legal Clinical Cannabis") (see http://acmed.org/data/pdf/2002-01-1.pdf). There is no legitimate rationale either medically, scientifically, ethically or legally, not to exempt cannabis from control under the CSA and regulate it like alcohol and tobacco.

Cannabis has been accepted as having medical use by 46 States. Cannabis has also been legalized for recreational use by 24 States because it is safer than either alcohol or tobacco, both of which are exempted from control under the CSA. In order to protect the health, safety and welfare of the Citizens of these States and every State:

- 1. Any rules implemented to regulate cannabis in schedule 3 of the CSA must not interfere with rights of the States to implement programs regarding medical and recreational Cannabis for their citizens.
- 2. In order to protect the health, safety and welfare of all US citizens, medical patients from all States must be allowed to have protected access to Cannabis without undue restrictions being implemented.
- 3. Regulations must be developed to allow legitimate Cannabis businesses and their employees access to banking.
- 4. Due to the broad range of therapeutic applications, research into the therapeutic use of Cannabis must be encouraged and appropriately funded.
- 5. In order to ensure that Medical Cannabis Patients have affordable access to needed medication, insurance companies should be required to cover the cost of Cannabis prescriptions with reasonable or zero co-pays, commensurate with other medications within their formularies.

6. In order to ensure these rules can be implemented properly, the Attorney General and DEA should exempt Cannabis from control under the CSA and allow it to be regulated by the States like alcohol and tobacco rather than moving Cannabis into Schedule 3, which could potentially limit medical access to Cannabis and cause harm to millions of Americans.

All notices to be sent pursuant to the proceeding should be sent to:

Rev. Bryan A. Krumm, CNP 733 Monroe St. NE Albuquerque, NM 87110 (505) 414-8120

Respectfully yours,

Submitted this 19'th day of June, 2024 by USPS priority mail

June 19, 2024

Filed: 02/17/2025

The Honorable Anne Milgram Administrator Drug Enforcement Administration Docket No. DEA-1362 8701 Morrissette Drive Springfield, Virginia 22152 (571) 362-3249 nprm@dea.gov

RE: Request for Hearing Period on the Proposed Rule Rescheduling Marijuana, Docket No. DEA-1362

Dear Administrator Milgram:

As your predecessors and knowing the importance of the issue at hand, we respectfully request a hearing on the Proposed Rule announced on May 21, 2024, that would reschedule marijuana from Schedule I to Schedule III under the Controlled Substances Act (CSA). Given the magnitude of the impact of the proposed rule and considering we face an unprecedent drug overdose crisis in this country, we write to emphasize that a hearing on this rulemaking is in the public interest.

First, changing marijuana to Schedule III is likely the most consequential rulemaking DEA has ever attempted. Apart from the merits of rescheduling marijuana, it is undeniable that the decision has national and international significance. The rule proposes to change the definition of currently accepted medical use, as well as change the way the federal government implements our international treaty obligations under the Single Convention. It would be the most significant relaxation of narcotics restrictions in the history of the CSA. Such a sweeping change should be undertaken only on a robust administrative record. That is why Congress required that such decisions be made on the record and with opportunity for a hearing. It is hard to imagine a rule more appropriate for formal process than a proposal to loosen federal restrictions on marijuana.

Second, a hearing would enhance DEA's evaluation of the important sociological and scientific issues at stake. As DEA made clear in the Proposed Rule, additional data and rigorous scientific analysis is needed to determine whether marijuana is appropriately placed into Schedule III. Sifting through the competing claims about marijuana's pharmacological effects, potential for abuse, and implications for public safety, are best done at a hearing. It would allow outside experts to offer their view of the latest evidence and be subjected to cross-examination. It would allow local leaders, law enforcement groups, and other advocacy organizations to speak to the complexity of this issue.

Third, it is important to assess how this major change in drug policy could impact the ongoing and devastating drug abuse crisis facing this country. As the 2024 National Drug Threat Assessment highlighted, the United States is battling the deadliest drug threat it has ever faced, one that is fueled by fentanyl.

We appreciate the complexity of this issue and how it relates to the mission of DEA and believe that a public hearing on this proposal would enhance transparency, integrity, and public confidence in this process, regardless of what final resolution is reached.

Sincerely,

The Honorable Peter B. Bensinger
DEA Administrator 1976-1981
The Honorable Asa Hutchinson
DEA Administrator 2001-2003;
Department of Homeland Secur

Department of Homeland Security,
The Honorable John C. Lawn
Under Secretary for Border and
Transportation Security 2003-2005

The Honorable Robert C. Bonner

DEA Administrator 1990-1993;
Commissioner, United States Customs
Service 2001-2003; Commissioner,

The Honorable Karen P. Tandy
DEA Administrator 2003-2007

The Honorable Michele M. Leonhart

United States Customs and Border DEA Administrator 2010-2015; Protection 2003-2005 DEA Acting Administrator 2007-2010

The Honorable Donnie R. Marshall
DEA Administrator 1999-2001
The Honorable Robert Patterson
DEA Acting Administrator 2017-2018

The Honorable Timothy J. Shea DEA Acting Administrator 2020-2021

Filed: 02/17/2025

(All signature concurrences are on file)

CC: Hearing Clerk/OALJ

DEA Federal Register Representative/DPW

Drug Enforcement Administration

8701 Morrissette Drive

Springfield, Virginia 22152



June 19, 2024
Drug Enforcement Administration
Attn: Hearing Clerk/OALJ
8701 Morrissette Drive
Springfield, Virginia 22152

Subject: Request for Hearing

Dear Sir:

The undersigned Minority Cannabis Business Association (MCBA) hereby requests a hearing in the matter of: 21 CFR Part 1308; Docket No. DEA-1362; A.G. Order No. 5931-2024; Schedules of Controlled Substances: Rescheduling of Marijuana; ACTION: Notice of proposed rulemaking.

The undersigned MCBA has facilitated and collaborated with multiple national and state-based organizations and associations since early 2022 to form an Equity Policy Roundtable, conducting ongoing discussions and producing solution-oriented work products, with the mission of providing sensible and workable regulatory solutions regarding cannabis regulation in multiple states. This Roundtable has a deep collective understanding of these systems and their impact on patients, businesses, youth, and the community at large, particularly in relation to the way in which rules and regulations are implemented on a practical level.

We are requesting a public hearing to evaluate the interplay and inter-jurisdictional relationship between state-level medical programs and a new Schedule 3 regulatory framework. Our request is with the purpose of addressing these matters so that medical programs can be enhanced and research on efficacy can be properly expanded in the advent of the rescheduling of cannabis. We are able to provide information and testimony as to the impact of these considerations, particularly regarding the following of the eight factors under consideration, as set forth in 21 U.S.C. 811(c) and laid out in the DEA Rescheduling Draft Docket: 1) The drug's actual or relative potential for abuse; 3) The state of current scientific knowledge regarding the drug or other substance; 4) Its history and current pattern of abuse; 5) The scope, duration, and significance of abuse; 6) What, if any, risk there is to the public health;

It is our position that without proper evaluation and understanding of the interplay and inter-jurisdictional relationship between state-level medical programs and a new Schedule 3 regulatory framework, the impact on public health has negative potential and that undesired outcomes of rescheduling would be likely.

All notices to be sent pursuant to the proceeding should be addressed to:



Minority Cannabis Business Association ATTN: Mike Lomuto 1300 I St NW. STE 400 E. Washington, DC 20005

Respectfully yours,
Mike Lomuto
Board Chair
Minority Cannabis Business Association

Co-Signed by Fellow Leaders of the Equity Policy Roundtable

Eric Foster

Minorities for Medical Marijuana National Policy Director for Cannabis and Hemp

Adrian Adams, EdD M4MM NYS Director CEO Ontogen Botanicals CBD

Scheril Murray Powell, Esq. Cannabis and Agricultural Attorney ASTM D37 Executive Committee Member Cannabis HR Council, Founder/CEO

Tavian Crosland Social Equity Empowerment Network

Mark Slaugh CEO of iComply, LLC

Frederika McClary Easley

MCBA Vice President
Executive Director of Cannabis Impact Fund
Council for Federal Cannabis Regulation (CFCR) DEI &
Access to Capital committee co-chair and secretary

Filed: 02/17/2025

Mary Jane Oatman

Indigenous Cannabis Industry Association, Executive Director

Colleen Mairead Hughes

NYC NORML, Deputy Director President, TRAEHNY Partnership & Development Corp

Sephida Artis-Mills

United Empowerment Party President & Co-Founder

June 19, 2024

Drug Enforcement Administration

Attn: Hearing Clerk/OALJ

8701 Morrissette Drive

Springfield, Virginia 22152

Drug Enforcement Administration

Attn: DEA Federal Register Representative/DPW

8701 Morrissette Drive

Springfield, Virginia 22152

Subject: Request for Hearing on Docket No. DEA-1362

Dear Sir/Madam:

The undersigned Phillip A Drum, PharmD hereby requests a hearing in the matter of Docket No. DEA-1362 the rescheduling of marijuana

Phillip A Drum, PharmD is a 38-year California licensed pharmacist who has spoken on, written on and performed research on marijuana and driving. He has spoken as a content expert to multiple safe driving programs, including California Highway Patrol (CHP) Drug Recognition Experts (DRE) Trainers and was appointed by Governor Gavin Newsom to a 3-year state-wide CHP Impaired Driving Task Force required by California Senate Bill 94. A report with 31 recommendations was generated and sent to the California Legislature in January 2021.

Dr Drum is willing to testify on the following topics as they related to marijuana/cannabis:

- 1. Marijuana/cannabis claims as a medicine,
- 2. Impact of marijuana/cannabis on driving,
- 3. Monitoring for marijuana/cannabis impaired driving,
- 4. Social and environment impacts of cannabis legalization,
- Pharmacokinetics and pharmacodynamics of THC and its metabolites, and

6. Drug-drug interactions with THC and CBD.

All notices to be sent pursuant to the proceeding should be addressed to:

Phillip A Drum, PharmD

789 Condor Dr

Martinez, CA 94553

phillipdrum a comeast net

Phillip A Drum, Pharm D

Respectfully yours.

App.541



TENNESSEE BUREAU OF INVESTIGATION

901 R.S. Gass Boulevard Nashville, Tennessee 37216-2639 (615) 744-4000 Facsimile (615) 744-4500 TDD (615) 744-4001



Filed: 02/17/2025

June 19, 2024

Filed via the Federal eRulemaking Portal Drug Enforcement Administration Attn: Administrator 8701 Morrissette Drive Springfield, VA 22152

Subject: Request for Hearing in Docket No. DEA-1362, "Schedules of Controlled Substances: Rescheduling of Marijuana"

Dear Administrator Milgram:

In accordance with 21 C.F.R. sections 1308.44(a) and 1316.47(a), the undersigned, David Rausch, Director of the Tennessee Bureau of Investigation (TBI), hereby requests a public hearing on TBI's behalf in the matter of: Docket No. DEA-1362; A.G. Order No. 5931-2024 Schedules of Controlled Substances: Rescheduling of Marijuana. The Proposed Rule at issue, 89 Fed. Reg. 44,597 (May 21, 2024), would reschedule marijuana from a Schedule I drug to a Schedule III drug under the Controlled Substances Act, 21 U.S.C. § 801, et seq.

TBI joins other groups in strongly opposing the Department of Justice's (DOJ) proposal to reschedule marijuana from Schedule I to Schedule III. As the chief law enforcement agency in Tennessee with significant responsibility for combating illicit and dangerous drug use, TBI has an important interest in this proceeding. A central concern is DOJ's apparent lack of adherence to the established Eight Factor Analysis for evaluating the scientific and medical basis of such a rescheduling. Any rescheduling should be based on comprehensive scientific research, which it appears the Proposed Rule lacks. Aside from the deviation in the rescheduling process, TBI has concerns about the criminal justice, public-health, and social consequences of increased prevalence of marijuana that rescheduling would inevitably produce in our State. These consequences, which have played out in other States after legalization in some form, include: the heightened risk associated with the use of genetically modified and synthetically manipulated marijuana; the lack of necessary regulatory, pharmaceutical, medical, scientific, and enforcement infrastructure to manage the reschedule; and the inability to regulate marijuana production and prevent organized crime from exploiting the market, among other problems.









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TENNESSEE BUREAU OF INVESTIGATION

901 R.S. Gass Boulevard Nashville, Tennessee 37216-2639 (615) 744-4000 Facsimile (615) 744-4500 TDD (615) 744-4001



Filed: 02/17/2025

In short, TBI has extensive experience with investigating drug-related offenses and believes rescheduling marijuana as currently proposed is not in the best interest of public health and safety and sets a dangerous precedent for future drug approvals. TBI would appreciate the opportunity to share and substantiate these concerns at a public hearing on the Proposed Rule.

All notices to be sent pursuant to the proceeding should be addressed to:

Director David Rausch

901 R.S. Gass Blvd.

Nashville, TN 37216

Respectfully yours,

Cc:

Drug Enforcement Administration Attn: Hearing Clerk/OALJ 8701 Morrissette Drive Springfield, VA 22152

Drug Enforcement Administration Attn: DEA Federal Register Representative/DPW 8701 Morrissette Drive Springfield, Virginia 22152









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United Empowerment Party

Sephida Artis-Mills

639 Russell Ave. Ste. 101 Meadville, PA 16335 Sephida@unitedempowermentparty.org (757)-663-3447

June 19, 2024

Drug Enforcement Administration

ATTN: DEA Federal Register Representative/DPW 8701 Morrissette Drive Springfield, VA 22152

Subject: Formal Request for Administrative Hearing on the Rescheduling of Cannabis

Dear Sir/Madam,

I am writing to you on behalf of the United Empowerment Party to formally request an administrative hearing regarding the proposal to reschedule cannabis to a Schedule III controlled substance under the Controlled Substances Act (CSA). The United Empowerment Party (UEP) is a federally recognized political party dedicated to first uniting the cannabis industry to protect small businesses along the supply chain from being pushed out by large corporations, excessive taxes and other regulatory conditions that make access limited to those who are economically disadvantaged.

We believe that rescheduling cannabis to a Schedule III is not only insufficient but also counterproductive. Instead, we urge the Drug Enforcement Administration (DEA) to consider a full deschedule of cannabis. The following points highlight the compelling reasons and benefits for descheduling cannabis entirely.

Numerous studies have demonstrated the therapeutic benefits of cannabis for a variety of medical conditions, including chronic pain, epilepsy, multiple sclerosis, reduction of potential organ rejection in transplant patients, and cancer-related symptoms. <u>Our own Federal government's National Institutes of Health (NIH) not only has thousands of articles on cannabis and its health effects on its websites, it is also funding cannabis research.</u>

A full deschedule will facilitate more comprehensive and unbiased research and allow healthcare providers to prescribe cannabis based on scientific evidence rather than legal restrictions. This will lead to improved patient outcomes that contribute to a better quality of life and a greater understanding of the plant's medical properties.

2. Economic Advantages

Descheduling cannabis will significantly benefit the economy. It will create new jobs, generate additional tax revenue, and reduce the costs associated with enforcing cannabis prohibition. The cannabis industry has already shown a profound economic impact in states where it is legal, contributing to economic growth, creation of jobs, development of new careers and community development. The number of full-time cannabis jobs is projected to grow to almost 800,000 by 2028, representing an annualized growth rate of 15% (Source-light Ministry-time-production-lings and Industry-time-production-lings are proposed and Industry-time-production-lines are proposed and Industry-time-proposed and Industry-time-production-lines are proposed and Industr

This is faster than the approximately 3-4% annual employment growth rate projected for the US economy as a whole from 2020-2028.

(source: https://www.bts.gov/opub/mir/2015/article/labor-force-projections-io-2024.htm)

Here are some key statistics:

- There are 440,445 full-time equivalent jobs supported by legal cannabis.
- The US cannabis industry is expected to reach almost \$40 billion in 2024.
- · Cannabis will add \$115.2 billion to the economy in 2024.

The first quarter of 2024 generated over \$20B in tax revenue across legal states. A nationwide deschedule would amplify these positive effects.

A big problem with rescheduling is trying to align the 38 state-legal cannabis programs with the current DEA infrastructure for administering Schedule III drugs. There is clearly no federal plan in place at this juncture on how to manage this process, and it potentially puts at risk one of the few sectors of our economy with strong growth prospects. As each state tries to determine whether parts or all of their current protocols and participants are nullified, rescheduling will have a negative impact on small businesses and jobs nationwide. As a nation, we should be supporting the growth of this industry, not slowing it down.

3. Criminal Justice Reform

The current classification of cannabis as a Schedule I controlled substance has led to the criminalization of millions of Americans, disproportionately affecting communities of color. Descheduling cannabis willreduce the number of non-violent offenders in the criminal justice system, alleviate prison overcrowding, and redirect law enforcement resources to more pressing public safety issues. It will also address the racial disparitles in drug enforcement that came as a direct result of the war on drugs.

Rescheduling does nothing to reduce the harm caused by the overpolicing of cannabis.

4. Regulatory Consistency

Rescheduling cannabis to a Schedule III would still impose significant regulatory burdens and inconsistencies. By fully descheduling cannabis, the federal government will allow states to regulate it in a manner similar to alcohol and tobacco. This can provide a clear and consistent regulatory framework, facilitating interstate commerce and ensuring product safety and quality through uniform standards and regulations.

5. International Perspective

Several countries, including Canada and Uruguay, have fully legalized cannabis, setting a global precedent. The United States should lead by example and align its policies with these progressive international standards. Descheduling cannabis will enhance the United States' standing in global drug policy and promote international cooperation on cannabis regulation and research.

6. Social Justice and Equity Empowerment

Descheduling cannabis will pave the way for social equity programs that address the harms caused by decades of prohibition. These programs can provide opportunities for those disproportionately impacted and harmed by cannabis criminalization, including expungement of criminal records and support for minority-owned businesses in the cannabis industry. It will foster a more just and equitable society.

Conclusion

In conclusion, rescheduling cannabis to a Schedule III falls short of addressing the harm done by the criminalization of cannabis and amplifying comprehensive benefits that descheduling offers, to include normalizing the medicinal use of cannabis. Descheduling cannabis is a necessary step to harness its medical, economic, and social benefits fully. It would promote scientific research, stimulate economic growth, advance criminal justice reform, ensure regulatory consistency, align with international standards, and foster equity empowerment.

I respectfully request an administrative hearing on this matter and implore the DEA to consider the overwhelming evidence supporting the full deschedule of cannabis. I am available to provide further information and participate in discussions to advance this crucial issue.

Thank you sincerely for your attention to this important matter.

Sincerely,

Sephida Artis-Mills

President & Co-Founder

United Empowerment Party

June 20, 2024

Filed: 02/17/2025

Drug Enforcement Administration Attn: Hearing Clerk/OALJ 8701 Morrissette Drive Springfield, VA 22152. Subject: Request for Hearing

Dear Sir or Madam:

On behalf of Doctors for Drug Policy Reform (the "Organization"), the undersigned, Bryon Adinoff, M.D., hereby requests a hearing in the matter of "Schedules of Controlled Substances: Rescheduling of Marijuana" (89 Fed. Reg. 44597) or to participate in same.

I. Introduction

Doctors for Drug Policy Reform, or D4DPR (formerly known as Doctors for Cannabis Regulation) supports removing cannabis in all its forms from the Controlled Substances Act. In the context of the proposed rule, however, it is the Organization's position that the medical, scientific, and other evidence supports a Schedule V (alternatively, schedule IV) classification for "marijuana," "marijuana extract," and "naturally derived delta-9-tetrohydrocannabinols" and requests a hearing or to participate in same in support of its position.

First, the Organization agrees that marijuana has a currently accepted medical use in treatment in the United States and should be removed from Schedule I. As the premier organization of health professionals and scientists specifically organized to provide expert evidence related to the responsible regulation of cannabis, the Organization is best positioned to present additional evidence to support that assessment and to contextualize evidence and argument to the contrary.

Second, while the Organization agrees with HHS that marijuana should be removed from Schedule I, it contends that the evidence, properly considered, supports a classification below Schedule III. Relative to substances in Schedule III and Schedule IV, marijuana has a low potential for abuse and lower psychological/physical dependence. In support of its position, the Organization intends to present testimony from two of its members with relevant expertise, Drs. Bryon Adinoff and David Nathan, and whose CVs/bios are attached. The HHS analysis failed to fully and properly evaluate the relative abuse potential and psychological/physical dependence of marijuana abuse compared to Schedule III, IV, and V drugs, even though the statute requires this analysis and prior scheduling actions involving other drugs have done it too. At the requested hearing, the Organization intends to provide testimony and evidence on this matter to assist the agency in its final determination.

The Organization notes that "abuse," "dependence," and marijuana terms in the statute. The use of statutory terms herein indicates no agreement on the propriety of their use in other contexts. For example, "drug abuse" is no longer a diagnosis in DSM-V and therefore, abuse should not be used by medical professionals.

June 20, 2024

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The Organization also seeks to offer testimony on the issue of the meaning and application of the statutory term "abuse," particularly as it relates to cannabis use. Both FDA and DEA in the past have applied a definition of "drug abuse" as the intentional, non-therapeutic use of a drug product or substance, even once, to achieve a desired psychological or physiological effect." Accordingly, "abuse potential" abuse potential refers to "the likelihood that abuse will occur with a particular drug product or substance with CNS activity."

These definitions, however, are not generally accepted by the medical profession. Rather, drug or substance abuse, as used in the statute, should be understood to capture use or excessive use of a drug in a way that is harmful or detrimental to self, society, or both.³ This difference is particularly important in assessing the research and epidemiological evidence. A drug like cannabis that is widely available is often used without a prescription but not in a way that is harmful. Indeed, there is currently no way to "prescribe" cannabis, so all cannabis use is used without a prescription.

The Administrative Procedure Act provides "as the orderly conduct of public business permits, an interested person may appear before an agency or its responsible employees for the presentation, adjustment, or determination of an issue, request, or controversy in a proceeding, whether interlocutory, summary, or otherwise, or in connection with an agency function." 5 U.S.C. § 555(b). It similarly provides that the "agency as a matter of policy shall provide for the exclusion of irrelevant, immaterial, or unduly repetitious evidence." 5 U.S.C. § 556.

Because the Organization would adversely affected by the proposed rule, has concrete interests that differ from other potential participants, intends to provide non-cumulative evidence to assist the agency's final determination, and is well-suited to cross-examine evidence put forward by industry and rescheduling opponents alike, it requests a rulemaking hearing or to participate in same in support of its position.⁴

See, for example, https://www.fda.gov/media/116739/download.

The legislative history and agency precedent indicates that a determination that "potential for abuse" should not "be determined on the basis of isolated or occasional nontherapeutic purposes," but rather "there must exist a substantial potential for the occurrence of significant diversions from legitimate channels, significant use by individuals contrary to professional advice, or substantial capability of creating hazards to the health of the user or the safety of the community." 76 Fed. Reg. 77330 at 336. Based on this definition, not all cannabis use, whether medicinal or recreational, would constitute abuse.

See Animal Legal Defense Fund, Inc. v. Vilsack, 237 F. Supp. 3d 15, 22-23 (D.D.C. 2017) (citing Nichols v. Bd. of Trustees of Asbestos Workers Local 24 Pension Plan, 835 F.2d 881, 896-97 (D.C. Cir. 1987)).

Filed: 02/17/2025

II. Interests of the person in the proceeding.

The Organization is a 501(c)(3) non-profit organization that serves as a global voice for licensed health professionals and scientists advocating for evidence-based drug policies and best practices that advance public health, reduce stigma, and minimize harm. Its website is located at https://www.d4dpr.org/.

In 2015, Dr. David Nathan founded the Organization as Doctors for Cannabis Regulation to bridge the gap between the policy of prohibition and the unregulated legalization of cannabis. The Organization has been dedicated to that mission ever since. Since that time, it has served as the premier national physicians' association committed to the responsible regulation of cannabis in the United States and abroad, a global advocate, and represents the voices of over 400 physicians and licensed medical practitioners, in support of evidence-based cannabis regulation and legalization. The Organization is comprised of doctors, nurses, pharmacists—many if not nearly all of whom are registrants.

The Organization is frequently called upon to provide expert testimony in significant legislative and administrative contexts unaffiliated with the cannabis industry. It provided testimony for the first-ever Congressional subcommittee hearing on cannabis legalization and on dozens state-level initiatives and bills pertaining to medical and adult-use cannabis. The Organization frequently collaborates with other advocacy groups to educate the public, including on rescheduling. The Organization is not affiliated with the cannabis industry.

As noted on its website, the Organization also offers curriculums on cannabis education, each of which has been carefully vetted by our D4DPR Board and Experts.

The Organization and its members not only have a particularized interest and are affected by the proposed rule, but are in the best position to provide relevant, material, and not unduly repetitious evidence sought by the agency.

III. Objections or issues concerning which the person desires to be heard.

As an organization of health care professionals and scientists formed years ago to bridge the gap between the policy of prohibition and the unregulated legalization of cannabis, the Organization is generally interested in participating a hearing central to its longstanding mission. The Organization's participation will ensure that the evidence presented by both industry and rescheduling opponents alike are placed in the proper medical and scientific context.

In addition to general participation, as to specific and particularized issues of interest to the Organization, the Organization wishes to be heard on the following two issues.

a. Physical and psychological dependence relative to Schedule III, IV, and V compounds and relative potential for abuse. The HHS recommendation states that marijuana was compared to controlled substances in schedule III (ketamine) and schedule IV (benzodiazepines, zolpidem, and tramadol), as well as to other schedule II

substances (fentanyl and hydrocodone). Without much additional explanation, the recommendation states that it "evaluated the totality of the available data and have concluded that it supports the placement of marijuana in Schedule III." It is unclear, however, whether and how HHS performed a relative potential for abuse and dependence analysis compared to Schedule III and IV substances.

b. The meaning of "abuse" / "abuse potential" and its application to marijuana. Historically, FDA and/or DEA has defined "drug abuse" as the intentional, non-therapeutic use of a drug product or substance, even once, to achieve a desired psychological or physiological effect." But this definition or concept is not generally accepted in the medical community, and what constitutes abuse with a culturally available and sanctioned substance cannot be based on whether, on occasion, an individual consumes the substance on their own initiative rather than based on medical advice. Just like few would consider having a glass of wine with dinner to be alcohol abuse, few medical professionals would seriously consider smoking marijuana once a week on Friday to relax after work to be "abuse." The definition of "abuse" and "abuse potential" is important because it undergirds the HHS findings with respect to marijuana's "potential for abuse." Properly considered, marijuana does not have a "potential for abuse" any greater than drugs in the benzodiazepine class (Schedule IV).

IV. Brief Statement on the Issues.

a. Physical and psychological dependence relative to Schedule III, IV, and V compounds and relative potential for abuse. The HHS recommendation does not appear to do a meaningful comparative analysis in assessing scheduling factor three, even though the statute demands that in determining a final scheduling placement among Schedules III, IV, or V, the agency must compare physical and psychological dependence among them.⁵ Notably, both agencies have done this analysis in the past. For example, the agency concluded in 2013 that Lorcaserin should be placed in Schedule IV (78 Fed. Reg. 26701), based on an abuse potential study comparing lorcaserin to zolpidem (Schedule IV) and ketamine (Schedule III). The agency concluded in 2005 that pregabalin warranted Schedule V placement because

For example, Schedule III, factor 3 (21 U.S.C. § 812(b)(3)(C)) is "Abuse of the drug or other substance may lead to moderate or low physical dependence or high psychological dependence," while Schedule IV, factor 4 (21 U.S.C. § 812(b)(4)(C)) is "Abuse of the drug or other substance may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in schedule III." To determine whether a drug properly is placed in Schedule III or IV, it is therefore necessary to consider the relative dependence of the substance compared to other substances in Schedule III. The same can be said of Schedules IV and V.

Filed: 02/17/2025

"withdrawal effects of pregabalin are less severe than with other substances currently controlled in Schedule IV." (70 Fed. Reg. 43633.)

The HHS analysis on relative abuse potential, reproduced below, is hard to understand:

[T]he rank order of these substances regarding harms does not consistently align with the relative scheduling placement of these drugs in the CSA due to the pharmacological differences between various classes of drugs.

There are a number of confounding factors that likely influence the adverse outcomes measured in various epidemiological databases and account for the rank ordering of the drugs evaluated on these measures. For example, each substance has associated with it a different population that abuse that substance, a different prevalence of abuse, and a different profile of severe adverse outcomes in a setting of nonmedical use and abuse. Thus, it is challenging to reconcile the ranking of relative harms associated with the comparators used in this evaluation when the rankings differ across various epidemiological databases, and when these rankings often do not align with the scheduling placement of these comparators under the CSA. To address these challenges, we evaluated the totality of the available data and have concluded that it supports the placement of marijuana in Schedule III.

The Organization does not believe this analysis is sufficient, and it intends to provide detailed testimony from two witnesses on the low physical and psychological dependence of cannabis relative to Schedule III and IV substances.⁶ In particular, the analysis does not properly compare cannabis to the benzodiazepine class in Schedule IV, and it is well documented that benzodiazepine abuse results in significant physiological and psychological dependence. The proposed rule similarly recognizes that the public health risk of benzodiazepines is substantially greater than the risk presented by cannabis. The evidence will show that compared to benzodiazepines, abuse of marijuana leads to limited physical dependence or psychological dependence relative to the drugs or other substances in schedule IV.

b. The meaning of "abuse" / "abuse potential" and its application to marijuana. Marijuana, like most drugs, can be "abused." But what constitutes "abuse" in the context of a culturally available and state-regulated substance cannot be based simply on whether, on occasion, an individual consumes the substance on their own initiative rather than based on medical advice, without any harm to the individual. Few would consider a glass of wine with dinner to be alcohol "abuse." Likewise, occasional marijuana consumption that presents no individual or societal harm is not "abuse." The

One witness has recognized expertise in addiction and substance use disorders. The other has expertise in cannabis policy and psychiatry.

Filed: 02/17/2025

proposed rule recognizes that "the vast majority of individuals who use marijuana are doing so in a manner that does not lead to dangerous outcomes to themselves or others." None of that is "abuse," and in assessing prevalence as part of a potential for abuse assessment, DEA should neither include medical uses of marijuana nor nonproblematic non-medical uses.

All notices to be sent pursuant to the proceeding should be addressed to:

Bryon Adinoff 812 S Gaylord St Denver, CO 80209

David L. Nathan, MD, DFAPA Princeton Psychiatry & Consulting, LLC 601 Ewing Street, Suite C-10 Princeton, NJ 08540

and

Matthew C. Zorn Yetter Coleman LLP 811 Main Street, Ste. 4100 Houston, TX 77002 mzorn@yettercoleman.com

Respectfully yours,

Bryon Adinoff, M.D.

President, Doctors for Drug Policy Reform



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CURRICULUM VITAE

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Education:

1983-1986 Medical Staff Fellow, Laboratory of Clinical Studies, Division of Intramural Clinical and Biological Research, National Institute on Alcohol Abuse and Alcoholism, Bethesda, MD

1979-1983 Psychiatry Residency, Tulane University Affiliated Hospitals, New Orleans, LA

1975-1979 M.D. - College of Human Medicine, Michigan State University, East Lansing, Michigan

1971-1974 B.G.S. - University of Michigan, Ann Arbor, Michigan

Faculty Appointments:

Clinical Professor, Department of Psychiatry, University of Colorado Anschutz Medical 2019-Center

2017-2019 Adjoint Professor, Department of Psychiatry, University of Colorado Anschutz Medical

Center

Graduate Faculty, Rehabilitation Counseling Psychology Program, UT Southwestern 2009-2018

Medical Center

2006-2018 Tenure, Department of Psychiatry, UT Southwestern Medical Center

2005-2018 Adjunct Professor of Brain Imaging Research, School of Behavioral and Brain Sciences,

University of Texas at Dallas

2000-2018 Member, Clinical Psychology Graduate Program, UT Southwestern Graduate School of

Biomedical Sciences

1998-2018 Professor, Department of Psychiatry, UT Southwestern Medical Center

Clinical Associate Professor, Department of Family Practice, University of North Texas 1998-2018

Health Science Center at Fort Worth

1995-2018 Distinguished Professor in Alcohol and Drug Abuse Research, Department of

Psychiatry, University of Texas Southwestern Medical Center at Dallas

1995-1998 Associate Professor, Department of Psychiatry, UT Southwestern Medical Center 1992-1995

Associate Professor, Department of Psychiatry and Behavioral Sciences, Medical University of South Carolina, Charleston, SC

1988-1992 Assistant Professor, Department of Psychiatry and Behavioral Sciences, Medical

University of South Carolina, Charleston, SC

1985-1988 Adjunct Assistant Professor, Department of Psychiatry, George Washington University,

Washington, DC

Hospital Appointments:

2014-2018 Attending Staff, UT Southwestern Medical Center, Dallas, TX

Licensure 2015-1996 - 2018

1989 - 1995

Colorado (#DR.0055904) Texas (#J9942) South Carolina (#14229) Filed: 02/17/2025

	Curriculum V	ïtae	Page 2
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	1997-2018	Attending Staff, Parkland Medical Center, Dallas, TX	
	1995-2018	Attending Staff, VA Medical Center, Dallas, TX	
	1994-1995	Attending Staff, Medical University of South Carolina, Charlesto	n, SC
	1988-1995	Attending Staff, VA Medical Center, Charleston, SC	
	1986-1988	Senior Staff Fellow, Laboratory of Clinical Studies, DICBR, Nati Abuse and Alcoholism, Bethesda, MD	onal Institute on Alcohol
	1983-1986	Ward Administrator, Alcohol Unit, Clinical Center, National Insti MD	tute of Health, Bethesda,
	1982-1983	Part-time Staff, East Louisiana State Hospital, Jackson, LA	
	1982-1983	Part-time Staff, New Orleans Adolescent Hospital, New Orleans	LA
	1981-1983	Part-time Staff, Charity Hospital, New Orleans, LA	, 51
	1980-1983	Part-time Staff, Veterans Administration Hospital, New Orleans	LA
		ve Appointments:	-24-1
	2013-2018	Director of Research, Mental Health, VA North Texas Health Ca	
	2005-;2018	Chief, Division on Addictions, University of Texas Southwestern Dallas	Medical Center at
	1995-2005	Director, Clinical Center for Addictive Diseases, University of To Medical Center at Dallas	exas Southwestern
	1997-2005	Medical Director, Substance Abuse Team, Mental Health, VA N System, Dallas	lorth Texas Health Care
	1996-1997	Member, Transition for Mental Health, VA Medical Center Dalla	s TX
	1995-1997	Chair, Substance Abuse Subcouncil for VISN #17 Mental Healt	
	1995-1997	Director, Chemical Addiction Program, VA Medical Center, Dall	
	1992-1995	Director, Substance Abuse Treatment Center, VA Medical Cen	
	1988-1992	Medical Director, Substance Abuse Treatment Center, VA Med	
	1900-1992	SC	icar center, chaneston,
	1986-1988	Chief, Unit of Outpatient Studies, Laboratory of Clinical Studies	DICRR National
	1300-1300	Institute on Alcohol Abuse and Alcoholism, Bethesda, MD	, Diobit, Hational
	1986	Acting Chief, Section of Clinical Science, Laboratory of Clinical	Studies DICBR
	1500	National Institute on Alcohol Abuse and Alcoholism, Bethesda,	
	Other Position	ons:	
	1975	Research Assistant, Ed Domino, M.D., Department of Pharmac	cology I afavette Clinic
	1070	Detroit, MI	lology, Lalayette Chine,
	1973-1974	Counselor, Drug Help, Ann Arbor, MI	
	1972-1973	Research Assistant, James Woods, Ph.D., Department of Phar	macology University of
	1012-1010	Michigan, Ann Arbor, MI	industry of
	Board Certif	ication:	
	2014	Addiction Psychiatry, Recertified	
	Dec. 31, 2003		
	March, 1993		
	November, 1		
	1979	FLEX	
		W-2/42(5)	

2006-2016

2005-2007

2002-2004 2001-2018

1998-2001

System

Curriculum V	Vitae Page 3
Bryon H. Ad	inoff
1985 - 1988	Washington, DC (#15002)
1983 - 1988	Maryland (#D30259)
1979 - 1983	Louisiana (AA-93-82627)
Professiona	
	llege of Neuropsychopharmacology, Fellow
	ychiatric Association, Distinguished Life Fellow
	sociation of Addiction Psychiatry, Founding Member, Distinguished Fellow
Doctors for C	Cannabis Regulation, Founding Member, President
Administrat	ive
2022-	President, International Society of Addiction Journal Editors (ISAJE)
2020-2022	Vice-President, International Society of Addiction Journal Editors (ISAJE)
2018-	Member, Legislative Committee, Colorado Psychiatric Society
2018	Member, Diversion Prevention and Awareness Task Force, Parkland Memorial Hospital
2018-	Board of Directors, International Society of Addiction Journal Editors (ISAJE)
2015-2017	Ethics Committee, American College on Neuropsychopharmacology
2015-2018	Co-chair, New Investigators Award Committee, VA North Texas Health Care System
2015-2017	Member (Alternate), Research and Development Committee, VA North Texas Health Care System
2014-2018	Chair, Committee on Practitioner Peer Review Assistance (COPPRA), Combined Parkland Memorial Hospital – UT Southwestern Medical Center
2014-2017	Member, Opioid Safety Initiative, VISN17, Veterans Hospital Administration
2013-2018	Chair, Mental Health Research Committee, VA North Texas Health Care System
2012-2013	Member, Chair's Subcommittee on the Advising System, Department of Psychiatry, UTSW
2012-2017	Chair, Substance Use Disorder Leadership Council, VISN17, Veterans Hospital Administration
2010-2018	Co-director, Region VIII, American Academy of Addiction Psychiatry
2012	Member, Program Committee, Research Society on Alcoholism
2010-2014	Vice-chair, Committee on Practitioner Peer Review Assistance (COPPRA), Combined
	Parkland Memorial Hospital – UT Southwestern Medical Center
2011-2013	Coordinator for UT Southwestern Medical Center, Metroplex Day
2010-2017	Treasurer, Executive Board, Texas Research Society on Alcoholism
2010-2011	Member, Psychiatric Research Education Program Mentor Committee, Department of Psychiatry, UT Southwestern
2008-2011	Member, Human Research Committee, American College on Neuropsychopharmacology
2007-2009	Chair, Research Development Committee, NIDA Clinical Trials Network
2006-2018	Member, Accreditation and Promotion Committee, Department of Psychiatry, UT

Member, Executive Committee, Department of Psychiatry, UT Southwestern Member, Research Development Committee, NIDA Clinical Trials Network

Member, Public Policy Section, American Association of Addiction Psychiatry

Chair, Clinician's Promotion Board, Mental Health Service, VA North Texas Health Care

Member, Task Force on Addictive Disorders, Texas Society of Psychiatric Physicians

Bryon H. Adinoff 1999-2011 Member, Committee on Practitioner Peer Review and Rehabilitation (COPPRA), Combined Parkland Memorial Hospital – UT Southwestern Medical Center Chair, Addiction Council, VA North Texas Health Care System Member, Continuity of Care Committee, VA North Texas Health System Member, Substance Abuse Program Guide Task Force, VA Central Office Member, Institutional Review Board for Human Research, Medical University of South Carolina, Charleston, SC Member, Institutional Review Board for Human Research, Medical Center, Charleston, SC Member, Pharmacy and Therapeutics Committee, VA Medical Center, Charleston, SC Member, Pharmacy and Therapeutics Committee, VA Medical Center, Charleston, SC Chairman, Medical Record Review Committee, Department of Psychiatry and Behavioral Sciences, Medical University of South Carolina Sciences, Medical University of South Carolina Member, Substance Abuse Executive Committee, Department of Psychiatry and Behavioral Sciences, Medical University of South Carolina Member, Strategic Planning Committee, VA Medical Center, Charleston, SC 1999-1993 Member, Drug Utilization Review Committee, VA Medical Center, Charleston, SC 3989-1994 Alternate Member, Institutional Review Board for Human Research, Medical University of South Carolina Member, Medical Record Review Committee, Charleston VA Medical Center Charleston Statistice on Alcohol and Alcoholism Member, Medical Research Review Panel, Clinical Center, National Institutes of Health Member, Quality Assurance Coordinators, Clinical Care, National Institutes of Health Member, Scientific Advisory Committee, Medical Marijuana Research Grant Program, Colorado Department of Public Health and Environment, 2018 Member, Scientific Advisory Committee, Medical Marijuana Research Grant Program, Colorado Department of Public Health and Environment, 2018 Member, Special Emphasis Panel/Scientific Review Group, Office of Research and Development, Department of Veterars Affairs (2019) Member, Special Emphasis Panel (ZAA1), Cente	Curriculum '	Vitae	Page 4	
Combined Parkland Memorial Hospital – UT Southwestern Medical Center 1997-2018 1997-2018 1997-2018 Member, Continuity of Care Committee, VA North Texas Health Care System Member, Substance Abuse Program Guide Task Force, VA Central Office Member, Institutional Review Board for Human Research, Medical University of South Carolina, Charleston, SC Member, Pharmacy and Therapeutics Committee, VA Medical Center, Charleston, SC Member, Pharmacy and Therapeutics Committee, VA Medical Center, Charleston, SC Medical Review Officer, VA Medical Center Charleston, SC 1991-1993 Member, Substance Abuse Executive Committee, VA Medical Center, Charleston, SC Member, Strategic Planning Committee, VA Medical Center, Charleston, SC Member, Drug Utilization Review Committee, VA Medical Center, Charleston, SC Member, Drug Utilization Review Committee, VA Medical Center, Charleston, SC Member, Drug Utilization Review Committee, VA Medical Center, Charleston, SC Member, Drug Utilization Review Committee, VA Medical Center, Charleston, SC Member, Medical Record Review Committee, VA Medical Center, Charleston, SC Member, Medical Record Review Committee, VA Medical Center, Charleston, SC Member, Medical Record Review Committee, VA Medical Center, Charleston, SC Member, Medical Record Review Committee, Charleston VA Medical Center Chairman, Institute Clinical Research Subpanel, Laboratory of Clinical Studies, DICBR, National Institute on Alcohol and Alcoholism Member, Member, Medical Member, Subpanel, Clinical Center, National Institutes of Health Member, Quality Assurance Coordinators, Clinical Center, National Institutes of Health Member, Scientific Advisory Committee, Medical Marijuana Research Grant Program, Colorado Department of Public Health and Environment, 2018 Member, Scientific Advisory Committee, Medical Marijuana Research Grant Program, Colorado Department of Public Health and Environment, 2018 Member, Special Emphasis Panel/Scientific Review GG-57 P60), NIAAA (2013) Member, Center Review (GG-58 P50), NIAAA (2013) Member, Ne				
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1994-2000 Member, Continuity of Care Committee, VA North Texas Health System Member, Substance Abuse Program Guide Task Force, VA Central Office Member, Institutional Review Board for Human Research, Medical University of South Carolina, Charleston, SC Member, Pharmacy and Therapeutics Committee, VA Medical Center, Charleston, SC Member, Pharmacy and Therapeutics Committee, VA Medical Center, Charleston, SC Member, Pharmacy and Therapeutics Committee, VA Medical Center, Charleston, SC Member, Medical Review Officer, VA Medical Center, Charleston, SC Chalimman, Medical Record Review Committee, Department of Psychiatry and Behavioral Sciences, Medical University of South Carolina Member, Strategic Planning Committee, VA Medical Center, Charleston, SC Member, Drug Utilization Review Committee, VA Medical Center, Charleston, SC Alternate Member, Institutional Review Board for Human Research, Medical University of South Carolina Member, Medical Record Review Committee, Charleston VA Medical Center Chairman, Institute On Alcohol and Alcoholism Member, Medical Record Review Committee, Charleston VA Medical Center Chairman, Institute on Alcohol and Alcoholism Member, Quality Assurance Coordinators, Clinical Center, National Institutes of Health Member, Quality Assurance Coordinators, Clinical Center, National Institutes of Health Member, Quality Assurance Coordinators, Clinical Care, National Institutes of Health Member, Special Emphasis Panel/Scientific Review Group for Specialized Alcohol Research Centers, (2AA1 P50), NIAAA (2013) Member, Center of Excellence' Grant Program (P-50), (ZDA1 NXR-B), NIDA (2015) Member, Center Review (GG-58 P50), NIAAA (2013) Member, Center Review (GG-59 P50), NIAAA (2013) Member, Center Review (GG-58 P50), NIAAA (2013) Member, Neurobiology A Integrated Review Group, Office of Research and Development, Department of Veterans Affairs (2010) Chair, Neurobiology Therapy Alcohol and Drug Abuse Panel (PR093916), Peer Reviewed Medical Research Program (PRMRP), US Army Medical Research and	1997-2018			
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Member, Human Research Review Panel, Clinical Center, National Institutes of Health Member, Quality Assurance Coordinators, Clinical Care, National Institutes of Health Member, Quality Assurance Coordinators, Clinical Care, National Institutes of Health Member, Grant Award Opportunity, Institute of Cannabis Research (ICR), Colorado State University Pueblo, 2021 Member, Scientific Advisory Committee, Medical Marijuana Research Grant Program, Colorado Department of Public Health and Environment, 2018 Member, Scientific Advisory Committee, Medical Marijuana Research Grant Program, Colorado Department of Public Health and Environment, 2018 Member, Center of Excellence' Grant Program (P-50), (ZDA1 NXR-B), NIDA (2015) Member, Special Emphasis Panel/Scientific Review Group for Specialized Alcohol Research Centers, (ZAA1 P50), NIAAA (2013) Chair, Comprehensive Research Center Review (GG-57 P60), NIAAA (2013) Member, Center Review (GG-58 P50), NIAAA (2013) Ad-hoc reviewer (ZRG1) EMNR (2012) Temporary Member, (ZRG1), NIDA (2011) Chair, I/Start Special Emphasis Panel (ZDA1), NIDA (2009, 2010, 2012, 2013, 2014, 2015) Temporary Member, Neurobiology A Integrated Review Group, Office of Research and Development, Department of Veterans Affairs (2010) Chair, Neurobiology/Therapy Alcohol and Drug Abuse Panel (PR093916), Peer Reviewed Medical Research Program (PRMRP), US Army Medical Research and Materiel Command, Department of Defense (2009) Temporary Member, Neurobiology 2 Integrated Review Group, Office of Research and Development, Department of Veterans Affairs (2009) Member, I/Start Review (ZDA1), NIDA (2008) Member, Special Emphasis Panel (ZAA1), Center for Scientific Review, NIAAA (2007) Member, Research Center Review Committee, Department of Veterans Affairs (2006) Chair, Special Emphasis Panel (ZoA1), Center for Scientific Review, NIAAA (2006) Member, Clinical and Treatment Subcommittee (AA3), Center for Scientific Review, NIAAA (2004-2008) Consultant, Training and Career Development Subcommittee, NIDA	1986-1988		el, Laboratory of Clinical Studies, DICBR,	
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 Chair, I/Start Special Emphasis Panel (ZDA1), NIDA (2009, 2010, 2012, 2013, 2014, 2015) Temporary Member, Neurobiology A Integrated Review Group, Office of Research and Development, Department of Veterans Affairs (2010) Chair, Neurobiology/Therapy Alcohol and Drug Abuse Panel (PR093916), Peer Reviewed Medical Research Program (PRMRP), US Army Medical Research and Materiel Command, Department of Defense (2009) Temporary Member, Neurobiology 2 Integrated Review Group, Office of Research and Development, Department of Veterans Affairs (2009) Member, I/Start Review (ZDA1), NIDA (2008) Member, Special Emphasis Panel (ZAA1), Center for Scientific Review, NIAAA (2007) Member, Research Center Review Committee, Department of Veterans Affairs (2006) Chair, Special Emphasis Panel, Biochemical Research Review Subcommittee (ZAA1 CC), Center for Scientific Review, NIAAA (2005) Member, Clinical and Treatment Subcommittee (AA3), Center for Scientific Review, NIAAA (2004-2008) Consultant, Training and Career Development Subcommittee, NIDA (2002) 		THE REPORT OF THE PARTY OF THE		
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Member, Research Center Review Committee, Department of Veterans Affairs (2006) Chair, Special Emphasis Panel, Biochemical Research Review Subcommittee (ZAA1 CC), Center for Scientific Review, NIAAA (2005) Member, Clinical and Treatment Subcommittee (AA3), Center for Scientific Review, NIAAA (2004-2008) Consultant, Training and Career Development Subcommittee, NIDA (2002)			fic Review, NIAAA (2007)	
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		Training and Career Development Subcommittee	e, NIDA (2002)	

Page 5

Member, NIDA Special Emphasis Panel, Medication Development Panel (1999)
Member, Site Review, Alcohol Research Center, NIAAA (1998)
Member, Research Advisory Group, Department of Veteran Affairs (1993-1995)
Consultant, Fellowship Programs in Substance Abuse Treatment, Department of Veteran Affairs (1994)

Editorial Activities

2012- Editor-in-Chief, The American Journal of Drug and Alcohol Abuse 2007-2011 Editorial Board, The American Journal of Drug and Alcohol Abuse

Journal Reviews

Editorial Advisory Board, Sci-Mat

Advisor, Handbook of Psychiatric Measures and Outcomes, APA

Tenth Special Report to the U.S. Congress on Alcohol and Health, NIAAA Addiction

Consultant, WHO, Guidelines for Psychosocially Assisted Pharmacotherapy of Opioid Dependence

Guest Field Editor, International Journal on Neuropsychopharmacology

Alcohol and Alcoholism

Alcoholism: Clinical and Experimental Therapeutics

Alcohol Health & Research World

American Journal of Psychiatry

American Journal of Addictions

American Journal of Cardiology

Archives of General Psychiatry

Biological Psychiatry

CNS Drugs

Drug and Alcohol Dependence

Drugs, Habits, and Social Policy

Harvard Review of Psychiatry

Hormones and Behavior

JAMA

JAMA Network Open

Journal of Clinical Psychiatry

Journal of Clinical Psychopharmacology

The Journal of Critical Illness

Journal of Substance Abuse Treatment

Medical Toxicology

Neuro/mage

Neuropsychopharmacology

Pharmacology, Biochemistry, and Behavior

Psychiatry Research

Psychoneuroendocrinology

Psychiopharmacology

Grant's

2017-2018	Consultant, National Institute on Alcohol Abuse and Alcoholism. R43. Aware (A wearable awareness with real-time exposure): Rapid Wearable Alcohol Diagnostics. \$250,000. (PI: Sriram Muthukumar)
2013-2016	Principal Investigator, National Institute on Drug Abuse. R21. "Lidocaine infusion as a
	treatment for cocaine relapse and craving." \$275,000.
2012-2015	Co-Investigator, National Institute on Drug Abuse. K08. "Cardiovascular risks of prescription amphetamine use in a national veterans study." \$450,000 (Pl: Arthur

Curriculu	m Vitae
Bryon H.	Adinoff

	Westover)
2012-2014	Principal Investigator, National Institute of Arthritis and Muskoloskeletal and Skin Diseases (NIAMS). R21. "Striatal dopamine release in response to ultraviolet light in compulsive tanner." \$230,000.
2012 2017	
2013-2017	Co-investigator, National Institute on Drug Abuse. R01. Genetic and environmental modulators of the brain's response to marijuana cues. \$1,865,000 (PI: Francesca Filbey).
2011-2012	Co-investigator, University of North Texas. "Exercise intervention for
	psychoneuroendocrine comorbidities and relapse prevention in women recovering from substance abuse." (Pl: Vingren)
2012-2013	Co-investigator, National Institute on Drug Abuse. R03. "Independent Component
	Analysis Based Support Vector Machine Classification Method: Application to functional MRI data from cocaine-addicted patients." \$100,000 (PI: Mutlu Mete)
2012-2014	Co-Investigator, American Heart Association, "Cardiovascular Risks of Prescription
	Amphetamine Use in Adults". \$70,000 (PI: Arthur Westover)
2010-2012	Co-investigator, National Institute on Drug Abuse, U10 "Clinical Trials Network: Texas Node." \$1,000,000
2009-2012	Co-investigator, Department of Veteran Affairs, Merit Review. "Extinction of Fear
	Memories with Glucocorticoids in Veterans with PTSD." \$745,550 (PI: Alina Suris)
2007-2012	Principal Investigator, National Institute on Drug Abuse, R01 "Impulsivity, Neural
	Deficits, and Cocaine Relapse." \$1,000,000.
2007-2012	Principal Investigator, Integrative Neuroscience Initiative on Alcoholism-East, National
	Institute on Alcohol Abuse and Alcoholism. U01 "Stress, HPA Axis Dysfunction, and Relapse in Alcoholism." \$1,150,000
2006-2010	Principal Investigator, Department of Veteran Affairs, Merit Review. "Trauma, Stress,
	and Persistence of HPA Axis Dysregulation in Alcoholism," \$600,000
2005-2010	Principal Investigator, National Institute on Drug Abuse, U10 "Clinical Trials Network: Texas Node," \$3,550,000
2005-2007	Co-Investigator, National Institute on Alcohol Abuse and Alcoholism. R01. Naltrexone for Bipolar Disorder and Alcohol Dependence," \$275,000 (PI: Brown)
2005-2007	Co-Investigator, National Association for Research of Schizophrenia and Depression
	(NARSAD), Young Investigator Award "Memory Reconsolidation Interference in PTSD." \$120,000 (PI: Alina Suris)
2005	Principal Investigator, Department of Veterans Affairs, Career Development
	Enhancement Award, "Functional Magnetic Resonance Imaging (fMRI) in the Addictive Disorders," \$80,000.
2004-2009	Principal Investigator, National Institute on Drug Abuse, R25 "Psychiatrist Research
	Education & Training in Drug Abuse." \$1,400,000
2004-2009	Co-investigator, National Institute on Mental Health, R01 "Stress and Risk for Substance
	Abuse in Adolescents" \$1,250,000 (PI: Uma Rao)
2004-2009	Co-investigator, National Institute on Mental Health, R01 "Neuronal Risk Markers for
	Nicotine Dependence in Youth" \$1,250,000 (PI: Uma Rao)
2003-2005	Principal Investigator, Integrative Neuroscience Initiative on Alcoholism-East, National
	Institute on Alcohol Abuse and Alcoholism. U01 "fMRI of Stress, HPA Axis, and Limbic
	Function in Alcoholism." \$100,000
2003-2006	Principal Investigator, National Institute on Drug Abuse, R01 "Limbic Sensitivity in
	Cocaine Addiction." (competitive renewal) \$750,000
2001-2007	Co-investigator, National Institute on Mental Health, R01 "Risk for Substance Abuse in Depressed Adolescents" \$1,500,000 (PI: Uma Rao)
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Curriculum V	Vitae Page 7
Bryon H. Ad	
1999-2004	Co-Investigator, National Institute on Drug Abuse, R01 "Cocaine and Sympathetic Nervous Activity in Humans." \$880,000
1999-2000	Principal Investigator, National Institute on Drug Abuse, "Learned Helplessness Model of Cocaine Withdrawal", \$40,000
1998-2003	Principal Investigator, National Institute on Alcohol Abuse and Alcoholism, R01 "Pharmacologic Dissection of the HPA Axis in Alcoholism." \$755,000
1998-2003	Director, Nancy Hogan Boyd Dual Diagnosis Fellowship Program, \$120,000
1998-2001	Principal Investigator, National Institute on Drug Abuse, R01 "Limbic Sensitivity in Cocaine Addiction." \$675,000
1996-2001	Participating Investigator, VA Cooperative Study, "Naltrexone in the Treatment of Alcoholism". \$150,964
1998-2003	Co-Investigator, Department of Veterans Affairs, Merit Review "In Vivo Neurochemistry of Stress: Alcohol and Learned Helplessness." \$179,000 (PI: Fred Petty)
1995-1997	Principal Investigator, National Institute on Drug Abuse, R21 "Limbic Sensitivity in Cocaine Addiction." \$104,000
1994-1995	Principal Investigator, MUSC University Research Committee, "Pituitary-Adrenal Axis Disturbances in Alcoholism." \$12,000
1992-1997	Co-Investigator, National Institute on Drug Abuse, "Carbamazepine Treatment in Cocaine Abusers," \$349,712 (PI: Kathleen Brady)
1993-1994	Co-Investigator, Kabi Pharmacia, "Usefulness of carbohydrate deficient transferrin in monitoring alcohol dependent patients during treatment and/or detoxification." \$70,000 (PI: Ray Anton)
1989-1994	On-Site Coordinator, National Institute on Alcohol Abuse and Alcoholism, "Project MATCH: Matching Alcoholics to Client Heterogeneity," \$375,385
1988-1991	Principal Investigator, Upjohn, "Double-Blind Drug Study of Ethanol Withdrawal Syndrome," \$60,000
Teaching/E	
2017, 2018,	
	Invited Mentor, American Psychiatric Association Research Colloquium, (May 21, 2017, San Diego, CA; May 6, 2018, New York City, NY; May 2, 2021, Virtual; May 22, 2022, New Orleans)
2016-2017	Addiction Lectures for MS1-MS2 Class, UT Southwestern Medical Center
2014-2018	Co-director, Dallas Addiction Leadership Training (DALT) Fellowship (VA
,	Interdisciplinary Advanced Fellowship in Addiction Treatment), VA North Texas Health Care System
2007	Course Director, AAAP Review Course in Addiction Psychiatry, Coronado, CA, December 1-2, 2007.
2006	Course Director, AAAP Update in Addiction Psychiatry, Ft. Worth, TX, September 29-30, 2006.
2005	Course Director, AAAP Update in Addiction Psychiatry, San Francisco, CA, February 11-13, 2005, and Atlanta, GA, February 25-27, 2005
2003	Course Co-Director, AAAP Review Course in Addiction Psychiatry, Denver, CO. January 18-19, 2003
2002	Course Director, Annual Addiction Update, NOVA 2002. Dallas, TX. February 22-23, 2002.
2002	Course Co-Director, AAAP Review Course in Addiction Psychiatry, Kansas City, MO. February 2-3, 2002.
2001	Course Co-Director, Annual Addiction Update, NOVA 2001. Dallas, TX. February 14-15, 2001.

Page 8

Curriculum Vitae

Bryon H. Ad	linoff
2000	Course Co-Director, Annual Addiction Update, NOVA 2000. Dallas, TX. February 4-5, 2000
2000-2018	Associate Director, Addiction Psychiatry Fellowship, UT Southwestern Medical Center
1997-2000	Director, Addiction Psychiatry Fellowship, UT Southwestern Medical Center
1995 -1999	Supervisor, Interdisciplinary Substance Abuse Fellowship Research Project, Dallas VAMC
1993	Physician Planner, Regional Medical Education Center, Department of Veterans Affairs
1992-2007	Clinical supervision of psychiatry residents and medical students
1992-2003	Psychotherapy supervision of psychiatry residents
1992-1993	Supervision of clinical case conferences and inservices for clinical staff and trainees, Substance Abuse Treatment Center, VA Medical Center
1992	Participation in Regional Medical Education Center courses, Veterans Administration
1988-1995	Participation in Substance Abuse Seminar Series, psychiatry residents, Medical Univ South Carolina
1988-1993	Participation in Interviewing Skills Course, 1st year medical students, Medical Univ. South Carolina
1988-1993	Participation in Psychiatry Lecture Series, 3rd year medical students, Medical Univ
4-4- 4-6-	South Carolina
1988-1995	Primary supervision of Substance Abuse fellows, psychiatry house staff, and medical students at Substance Abuse Treatment Center, VA Medical Center
	Students at Substance Abuse Treatment Center, VA Medical Center
Honors and	Awards
2021	Distinguished Life Fellow, American Psychiatric Association
2017	Distinguished Fellow, American Academy of Addiction Psychiatry (FAAAP)
2012	American College of Neuropsychopharmacology, Fellow
2005	Dr. Kenneth Z. Altshuler Medical Leadership Award, Turtle Creek Manor
2004	American College of Neuropsychopharmacology, Full Member
2002	Alpha Omega Alpha Honor Medical Society
	Elected Alumnus, College of Human Medicine, Michigan State University
1999-2000	PGY-I Outstanding Teacher of the Year, Psychiatry Residents' Organization
	Southwestern Medical School
1997	GEICO Public Service Award for the Prevention and Treatment of Substance Abuse
1996-	"Crusader for Prevention", Medical/Health Department; Coalition '96, For Prevention of
	Substance Abuse; Greater Dallas Council on Alcohol and Drug Abuse
1991-1992	Psychiatry Golden Apple Award, Psychiatry Clerkship, Medical University of South Carolina
1983-1986	NIAAA Fellowship
Non-profit	
2023-	President, Doctors for Drug Policy Reform (D4DPR)
2021-	Advisory Council, Kansas Cannabis Coalition
2021-2023	President, Doctors for Cannabis Regulation (DFCR)
2019-2021	Executive Vice President, Doctors for Cannabis Regulation (DFCR)
2018-	Treasurer, Doctors for Cannabis Regulation (DFCR)
2018-	Board of Directors, Doctors for Cannabis Regulation (DFCR)
2017-2018	Co-chair, State Regulatory Committee, Doctors for Cannabis Regulation (DFCR)
2017-	Colorado State Representative, Doctors for Cannabis Regulation (DFCR)
2013-2015	Member, Board of Directors, Mothers Against Teen Violence, Dallas, TX
1998	Moderator and Leadership Panel, Faces of Addiction: A Community Forum. Dallas, TX.
1998	Grand Award Judge, 49th International Science & Engineering Fair, Ft. Worth, TX

Page 9

1997	Member, Dual Diagnosis Task Force, Dallas, TX
1996-2001	Executive Board of Directors, Greater Dallas Council on Alcohol and Drug Abuse
1996-2001	Chair, Clinical Subcommittee, Greater Dallas Council on Alcohol and Drug Abuse
1995-1997	Scientific Advisor, Chemical Awareness Resources and Education, Park Cities, TX

Outside Interests

Bass Guitar: R/E Authority blues band; Jennifer Rose Band Advocate Circle, Museum of Contemporary Art, Denver (2021) Contemporary Collectors Circle, Denver Museum of Art (2019-) Directors Council, Ft. Worth Museum of Modern Art (2005-2018) Docent, Ft. Worth Museum of Modern Art (2005-2018)

Peer-Reviewed Articles and Reviews

- Domino EF, Gahagan S, Adinoff B, Kovacic B. Effects of various neuroleptics on rabbit hyperthermia induced by DMT and d-amphetamine. <u>Arch Int Pharmacodyn Ther</u> 226:30-7, March, 1977.
- Schwartz B, Winstead D, Adinoff B: Circumscribed visual processing in schizophrenics. <u>Biol Psychiatry</u> 18:1311-1320, 1983.
- Zadina J, Kastin A, Coy D, Adinoff B: Developmental, behavioral, and opiate receptor changes after prenatal or postnatal B-endorphin, CRF, or Tyr-MIF-1. <u>Psychoneuroendocrinology</u> 10:367-383, 1985.
- Adinoff B, Majchrowicz E, Martin PR, Linnoila M: The benzodiazepine antagonist RO 15-1788 does not antagonize the ethanol withdrawal system. <u>Biol Psychiatry</u> 21:643-649, 1986.
- Johnson JJ, Adinoff B, Bisserbe JC, Martin PR, Rio D, Rohrbaugh JW, Zubovic E, Eckardt M: Assessment of alcoholism-related organic brain syndromes with positron emission tomography. <u>Alcohol Clin Exp Res</u> 10:237-239, 1986.
- Martin PR, Adinoff B, Weingartner H, Mukherjee AB, Eckardt MS: Alcoholic organic brain disease: Nosology and pathophysiologic mechanisms. <u>Prog Neuropsychopharmacol Biol</u> <u>Psychiatry</u> 10:147-164, 1986.
- Rohrbaugh JW, Stapleton JM, Parasuram R, Zubovic EA, Frowein HW, Varner JL, Adinoff B, Lane EA, Eckardt MJ, Linnoila M: Dose-related effects of ethanol on visual sustained attention and event-related potentials. <u>Alcohol</u> 4:293-300, 1987.
- Adinoff B: Hypothalamic-pituitary-adrenal axis functioning in recently abstinent alcoholics. In: M. Linnoila, moderator. Alcohol withdrawal and noradrenergic function. <u>Ann of Intern Med</u> 107:875-889, 1987.
- Roy A, Adinoff B, Roehrich L, Lamparski D, Custer R, Lorenz V, Barbaccia M, Guidotti A, Costa E, Linnoila M: Pathological gambling: A psychobiological study. <u>Arch Gen Psychiatry</u> 45:369-373, 1988.
- Roy A, Adinoff B, Linnoila M: Acting-out in normal volunteers: Negative correlation with 5-HIAA levels. <u>Psychiatry Res</u> 24:187-194, 1988.
- Adinoff B, Bone GHA, Linnoila M: Acute ethanol poisoning and the ethanol withdrawal syndrome. <u>Med Toxicol</u> 3:172-196, 1988.
- Linnoila M, Oliver J, Adinoff B, Potter WZ: High correlations of norepinephrine, dopamine, and epinephrine and their major metabolite excretion rates. <u>Arch Gen Psychiatry</u> 45:701-704, 1988.
- Rohrbaugh JW, Stapleton JM, Parasuram R, Frowein HW, Adinoff B, Varner JL, Lane EA, Eckardt MJ, Linnoila M: Alcohol intoxication reduces visual sustained attention. <u>Psychopharmacol</u> 96:442-446, 1988.
- George DT, Nutt DJ, Walker WV, Porges SW, Adinoff B, Linnoila M: Sodium lactate and hyperventilation substantially attenuate vagal tone in normal volunteers: a possible mechanism of panic provocation? <u>Arch Gen Psychiatry</u> 46:153-156, 1988.

- Nutt DJ, Adinoff B, Ravitz B, George DT, Flowers D, Eckardt M, Bone GHA, Martin PR. Linnoila M: CSF studies in alcoholics and violent offenders. <u>Aust Drug Alcohol Rev</u> 7:105-108, 1988.
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- Roy A, Lamparski J, De Jong B, Adinoff B, Ravitz D, George T, Nutt D, Linnoila M: Cerebrospinal fluid monoamine metabolites in alcoholic patients who attempt suicide. <u>Acta Psychiatr Scand</u> 81:58-61, 1990.
- Adinoff B, Martin PR, Bone GHA, Eckardt MJ, Roehrich L, George DT, Moss H, Eskay R, Linnoila M, Gold PW: Hypothalamic-pituitary-adrenal axis functioning and cerebrospinal fluid CRH and ACTH in alcoholics following recent and long term abstinence. <u>Arch Gen Psychiatry</u> 47:325-330, 1990.
- Roy A, DeJong J, Adinoff B, Linnoila M: CSF galanin in alcoholics, gamblers, and normal controls: A negative report. <u>Biol Psychiatry</u> 15:923-926, 1990.
- Roy A, DeJong J, Adinoff B, Barbaccia M, Costa E, Guidotti A, Linnoila M: CSF diazepambinding inhibitor in alcoholics and normal controls. <u>Psychiatry Res</u> 31:261-266, 1990.
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- "Treatment of the ethanol withdrawal syndrome." Crownsville Hospital Center. Crownsville, MD. April 16, 1988.
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- "Identification and Intervention in Substance Abuse." Internal Medicine Fall 1996, Loews Coronada Bay Resort. October 1, 1996
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- "Biology of Addiction." Presbyterian Hospital of Dallas. Dallas, TX. June 11, 1999.
- "Addiction Update." Sixth Annual Science of Family Medicine: A Review Course. UT Southwestern Medical Center. Dallas, TX. June 11, 1999.
- "Overview of Substance Abuse." Lubbock Area Dual Diagnosis Project. Lubbock, TX. July 6, 1999. "The Biology of Addiction." 42nd Annual Institute of Alcohol and Drug Studies. Austin, TX. July 27, 1999
- "HPA Axis Disturbances During Alcohol Withdrawal and Abstinence." Grand Rounds, Medicine Service. Salem VA Medical Center. Salem, VA. Sept. 3, 1999.
- "New Research on Alcoholism." Addiction Psychiatry Review Course. St. Louis, MS. Sept. 15, 1999. "Depression: Beyond Stereotype and Stigma." Projects in Knowledge. Dallas, TX. Oct. 2, 1999.
- "Update in Addiction." Grand Rounds. Terrell State Hospital. Terrell, TX. February 3, 2000

- "Translating Drug Abuse Research Into Practice: The NIDA Clinical Trials Network The Texas Node." Grand Rounds. University of Texas Southwestern Medical Center. Dallas, TX. Oct. 17, 2007.
- "Trauma and Alcoholism: The Stress Hormone Link?" Grand Rounds. Department of Psychiatry, University of New Mexico. Oct. 24, 2008.
- "Trauma, Stress, Alcohol, Genes and HPA Axis Disruptions: Is There An Additive Link?" Distinguished Speaker Seminar, Department of Clinical Sciences, UT Southwestern Medical Center, Dallas, TX. Feb. 12, 2008.
- "Impulsivity: What Is It, Who Has It, and What To Do About It." 2009 Update in Psychiatry: Common Challenges in Psychopharmacology. Medical University of South Carolina, Charleston, SC. May 30, 2009.
- "Impulsivity in the Addictive Disorders: The "Oops" Factor in Relapse." Grand Rounds. Department of Psychiatry, Vanderbilt University, Nashville, TN. Jan. 7, 2010.
- "The Re-wired Addicted Brain: Why It's Hard to Stop Using Nicotine, Alcohol and Other Drugs" Grand Rounds. Methodist Hospital Center, Dallas, TX. Feb. 4, 2010.
- "Trauma, Alcoholism, and Stress-Hormone Disruptions." Grand Rounds. John Peter Smith Hospital, Ft. Worth, TX. March 26, 2010
- "Translational Studies in Addicted Subjects: An Exploration of Non-dopaminergic Systems." Seminar, Department of Pharmacology and Neuroscience. University of North Texas Health Science Center. Ft. Worth, TX. March 30, 2010
- "Drug Use Without Craving: Impulsive Relapse in Addiction." Grand Rounds, Department of Neuropsychiatry and Behavioral Science, Texas Tech University Health Science Center. Lubbock, TX. March 29, 2011.
- "Shared Cortical-Limbic-Striatal Disruptions in Human Imaging Studies of Addiction." UTD 2012 Neuroscience Research Conference, Dallas, TX. April 13, 2012.
- "Clinical and Neurobiological Aspects of Impulsive Relapse." Continuing Educational (CE) program. Hazeldon Foundation. Center City, MN. July 18, 2012.
- "Neuroimaging in Addiction: Common Threads." Grand Rounds. Seton Medical Center. Austin, TX. Aug. 14, 2012.
- "Neuroimaging in the Investigation and Assessment of Substance Use Disorders." Texas Society of Psychiatric Physicians 56th Annual Convention. Galveston, TX. Nov. 10, 2012.
- "Cravings, Memories, and Addiction: A Critical Role for the Hippocampus?" Grand Rounds. Center for BrainHealth, University of Texas at Dallas. May 1, 2013.
- "Does Stress Really Make You Drink? The Biological Connection." Grand Rounds. Department of Psychiatry, UT Southwestern Medical Center. Dallas, TX. May 8, 2013.
- "DSM-5: Substance Use Disorders." Continuing Education Symposium. Department of Psychiatry, UT Southwestern Medical Center. Dallas, TX. July 20, 2013.
- "DSM-5: Substance Use Disorders." VA North Texas Health Care System. Dallas, TX. July 26, 2013.
 August 9, 2013.
- "Use of Certificate of Confidentiality (COC)." Research Matters. UT Southwestern Medical Center. Dallas, TX. April 2, 2014.
- "Does Stress Make You Drink?" Grand Rounds. Mental Health, VA North Texas Health Care System. Dallas, TX. July 17, 2014.
- "What More is Needed to Prove UV Radiation is Rewarding and Addictive." Grand Rounds. Department of Dermatology, UT Southwestern Medical Center. August 14, 2014.
- "What We're Learning About the Neuroscience of Addiction". Reinvesting in Justice: What Comes Next? Center for Court Innovation. Dallas, TX. November 12, 2015
- "Pharmacotherapy for Alcohol Use Disorders" Symposium on Medication as an adjunct versus monotherapy for the treatment of substance use disorders. Texas Research Society on Alcoholism, Dallas, TX. February 19, 2016.

- Adinoff B, Devous MD, Sr., Best SM, George MS, Alexander D, Payne KJ, "Orbitofrontal dysfunction in cocaine addiction: SPECT following IV procaine." Symposium on Addiction as a Disease of the Orbitofrontal Cortex. 39th ACNP Annual Meeting, San Juan, Puerto Rico. December 11, 2000.
- Adinoff B (Chair), Porrino L, Anton R, London E. Symposium on The orbitofrontal cortex and the addictions: Neuroimaging studies. Thirty-fourth Annual Winter Conference on Brain Research. Steamboat Springs, CO. January 20-27, 2001.
- Adinoff B. (Co-Chair). Symposium on What the General Psychiatrist Needs to Know about Addiction Psychiatry. American Psychiatric Association 2003 Annual Meeting, May 20, 2003. San Francisco, CA
- Adinoff B., "Neuroscience of addictions" in Symposium on What the General Psychiatrist Needs to Know about Addiction Psychiatry. American Psychiatric Association 2003 Annual Meeting, May 20, 2003. San Francisco, CA
- Adinoff B. (Chair). Symposium on Stress-Axis Reactivity to Pharmacologic Challenges: Defining the Disruption in the Drinkers and the Kids. 26th Annual Meeting of the Research Society on Alcoholism. June 22, 2003. Ft. Lauderdale, FL.
- Adinoff, B. "HPA axis sensitivity in abstinent alcohol dependent subjects: Isolation of axis pathology". Symposium on Stress-Axis Reactivity to Pharmacologic Challenges: Defining the Disruption in the Drinkers and the Kids. 26th Annual Meeting of the Research Society on Alcoholism. June 22, 2003. Ft. Lauderdale, FL.
- Adinoff B (Chair). Symposium on Sex Differences in the Addicted Brain: Neuroimaging Studies of Cocaine- and Alcohol-Dependent Men and Women. College on Problems on Drug Dependence Sixty-fifth Annual Scientific Meeting, Bal Harbour, FL. June 16, 2003.
- Adinoff B. (Chair). "Differing limbic sensitivity to a pharmacologic stimulus in cocaine-addicted men and women". Symposium on Sex Differences in the Addicted Brain: Neuroimaging Studies of Cocaine- and Alcohol-Dependent Men and Women. College on Problems on Drug Dependence Sixty-fifth Annual Scientific Meeting, Bal Harbour, FL. June 16, 2003.
- Adinoff B (Co-Chair). Symposium on Neuroimaging the Contrast: Cocaine Addicted Men vs. Women. American College of Neuropsychopharmacology 42nd Annual Meeting. San Juan, Puerto Rico. Dec. 10, 2003.
- Adinoff B., Devous M., Best SE., Harris TS. "Sex differences in limbic rCBF following both a saline and procaine stimulus in cocaine-addicted subjects". Symposium on Neuroimaging the Contrast: Cocaine Addicted Men vs. Women. American College of Neuropsychopharmacology 42nd Annual Meeting. San Juan, Puerto Rico. Dec. 10, 2003.
- Adinoff B. (Chair). Symposium on Suppression of the HPA Axis Stress-Response: Implications for Relapse. 12th World Congress on Biomedical Alcohol Research (ISBRA). Heidelberg/Mannheim, Germany. Oct. 1, 2004.
- Adinoff B. Krebaum S, Chandler P, Ye W. Brown MB, Williams M.J. "Blunted adrenocortical responsiveness in abstinent alcohol-dependent men". Symposium on Suppression of the HPA Axis Stress-Response: Implications for Relapse. 12th World Congress on Biomedical Alcohol Research (ISBRA). Heidelberg/Mannheim, Germany. Oct. 1, 2004.
- Adinoff B. "Impulsivity and Relapse." Symposium on Addiction and Psychiatry: Co-Occurring or Dual Diagnosis. 36th Annual Medical-Scientific Conference. American Society of Addiction Medicine. Dallas, TX. April 16, 2005.
- Adinoff B, Morrow AL, Williams MJ, Chandler PA. "oCRF stimulation of plasma deoxycorticosterone levels in abstinent alcohol-dependent subjects." Symposium on Are Neurosteroid Responses to Stress or Alcohol Withdrawal Related to Alcohol Drinking In Mouse, Rats, Monkeys or Man? 29th Annual Meeting of the Research Society on Alcoholism. Baltimore, MD. June 27, 2006
- Adinoff B (chair): Symposium on The Yin to the Dopaminergic Yang: Cholinergic Mechanisms in Cocaine Addiction. 40th Annual Winter Conference on Brain Research. Snowmass, Colorado, February 1, 2007.

Page 26

Filed: 02/17/2025

- AdInoff B (chair): Symposium on Assessing Stress in Alcoholics using Clinical Laboratory Paradigms. Research Society on Alcoholism, Chicago, IL. July 9, 2007.
- Adinoff B. "It's not a perfect world: A clinical researcher's perspective." Symposium on Translating Research: Basic and Clinical Dialogues. Research Society on Alcoholism, Chicago, IL. July 9, 2007.
- Sinha R, Wu H, Goeders NE, Adinoff B, Weiss F. Symposium on Organizing a Special Interest Group on Stress and Addiction. College on Problems on Drug Dependence Seventieth Annual Scientific Meeting. San Juan, Puerto Rico. June 15, 2008.
- Adinoff B. "Limbic disruptions identified by cholinergic probes in cocaine-addicted subjects." Symposium on The Acetylcholine System as Therapeutic in Drug Dependence. College on Problems on Drug Dependence 71st Annual Scientific Meeting. Reno, Nevada. June 23, 2009.
- Adinoff B. "Results from naturalistic and epidemiologic studies." Workshop on Is the Emperor Underdressed? Controversial Evidence that Alcohol Induces Drinking. Research Society on Alcoholism, San Antonio, TX. June 28, 2010.
- Adinoff B. "Limbic disruptions identified by cholinergic probes in cocaine-addicted subjects."

 Symposium on Cholinergic Mechanisms in Stimulant Dependence. Translational Psychiatry 1st Annual Scientific Meeting. Hall, Austria. July 10, 2010.
- Adinoff B, Taylor S, Conley R, Chezum L. "The certificate of confidentiality: Is the hassle worth it?"

 Symposium on Negotiating the Path to Approval: Finding Solutions to Common IRB Issues. ACNP
 49th Annual Meeting. Miami, FL. Dec 8, 2010.
- Denton W, Winhusen T, Lewis D, Walker NR, Adinoff B. "Family discord is associated with increased substance use for pregnant substance users." International Association for Relationship Research Mini-Conference on Health, Emotions and Relationships. Tucson, AZ. October 20-22, 2011.
- Adinoff B. (Chair) Symposium on Stress, Arousal and Alcohol Interactions: Clinical Studies in High-Risk Adolescents, Healthy Adults and Alcohol-Dependent Subjects. Alcoholism and stress: A framework for future treatment strategies. Volterra, Italy. May 5, 2011.
- framework for future treatment strategies. Volterra, Italy. May 5, 2011.

 Adinoff B, Yang H, Rao U, North CS, Xiao H, Business MS. "Unraveling the risks: Stress, trauma and alcohol effects upon biologic stress response systems and prospective relapse in alcohol dependent subjects". Symposium on Stress, Arousal and Alcohol Interactions: Clinical Studies in High-Risk Adolescents, Healthy Adults and Alcohol-Dependent Subjects. Alcoholism and Stress: A Framework for Future Treatment Strategies. Volterra, Italy. May 5, 2011.
- Adinoff B. "Stress, trauma and alcohol effects upon biological stress response systems and prospective relapse in alcohol dependent subjects." Symposium on Clinical Translational Research Linking the Neurobiology of Dysregulated Stress/Anxiety Systems to Alcohol Use Disorders. Research Society on Alcoholism. San Francisco, CA. July 26, 2012.
- Adinoff B, "Striatal-limbic suppression during anticipatory anxiety in alcohol-dependent men". Symposium on Applying Translational Research and Imaging to Treatment Strategies in Alcoholism. American College on Neuropsychopharmacology 51st Annual Meeting. Hollywood, FL. December 3, 2012.
- Price JL, Leonard D, Adinoff B. HPA Axis Dysfunction and Stress Implications in Relapse Severity. Symposium presented at the 24th Annual Scientific Meeting of the Texas Research Society on Alcoholism, San Antonio, TX. February 21, 2014.
- Adinoff B. Discussant. Symposium on Functionally relevant brain alterations in poly-substance abusers:

 Differences to mono-substance abusers, study challenges and research promises. Research
 Society on Alcoholism. San Antonio, TX. June 21, 2015
- Lewis B, Price JL, Adinoff B, Nixon SJ. "Exploring heterogeneity in the stress-alcohol diathesis across the lifespan." Organizer: Dr. Sara Jo Nixon. 4th Annual International Congress on Alcoholism and Stress, Volterra, Italy (May 9-12, 2017)
- Price JL, Frazier IR, Javors MA, Walker R, Nixon SJ, Adinoff B. Differences in HPA Function Between Black and White alcohol-dependent men. Organizer: Awards Committee. Symposium presented at

Page 27

- the 40th Annual Meeting of the Research Society on Alcoholism (RSA), Denver, CO. June 24-28, 2017.
- Adinoff B. Discussant. Symposium on Drug Addiction Treatment with Classic Hallucinogens. CPDD 80th Annual Scientific Meeting, San Diego, CA. June 11, 2018.
- Adinoff B. Chair and Discussant. Symposium on A New Era of Treating Substance Use Disorders with Psychedelics. AAAP Annual Meeting and Scientific Symposium. Bonita Springs, FL. December 6, 2018.
- Adinoff B. Chair. Symposium on Medical Cannabis from a Neuroscience Perspective: How Did We Get Here and Where Should We Go? American College on Neuropsychopharmacology 57st Annual Meeting. Hollywood, FL. December 12, 2018.
- Adinoff B. Maximizing the benefits and minimizing the harms of cannabis regulation. Symposium on Perspective on the Impact on Adolescents and Emerging Adults of Marijuana's Changing Legal Status and Access. Chair: Theodore Petti. 66th Annual Meeting of the American Academy of Child and Adolescent Psychiatry. Chicago, IL. Oct 19, 2019.
- Adinoff B. Chair. Symposium on The Racial Origins and Impact of the War on Drugs; How Do We Heal? AAAP Annual Meeting and Scientific Symposium. Virtual. December 12, 2021.
- Adinoff B. The role of addiction psychiatrists in righting the wrongs of the drug war. Symposium on *The Racial Origins and Impact of the War on Drugs: How Do We Heal?* AAAP Annual Meeting and Scientific Symposium. Virtual. December 12, 2021.
- Adinoff B. Chair. Symposium on *Treating Substance Use Disorders with Classical Psychedelics*. American Psychiatric Association Annual Meeting. New Orleans, LA. May 24, 2022.
- Adinoff B. Panel on <u>Cannabis Law Reform leading the way towards more effective drug control and the</u>
 <u>attainment of the Sustainable Development Goals</u>. United Nations 66th Commission on Narcotic
 Drugs (CND). Vienna, Austria. March 15, 2023.
- Adinoff B. Chair. Symposium on The Racist Origins and Impact of the War on Drugs. CPDD 85th Annual Scientific Meeting, Denver, CO. June 20, 2023.
- Adinoff B. The role of addiction researchers in righting the wrongs of the drug war. Symposium on The Racist Origins and Impact of the War on Drugs. CPDD 85th Annual Scientific Meeting, Denver, CO. June 20, 2023.

Other Presentations

- Heath RG, Franklin D, Adinoff B, Rubin W. "Comparison of schizophrenics with and without cerebellar vermal atrophy." Society of Biological Psychiatry, Boston, MA, May 18, 1980.
- Adinoff B, Majchrowicz E, Martin PR, Paul SM, Linnoila M. "The benzodiazepine antagonist Ro15-1788 does not antagonize ethanol withdrawal syndrome." Society of Biological Psychiatry, Dallas, TX, 1985.
- Adinoff B, Martin PR, Bone GHA, Linnoila M, Gold PW. "Response to corticotropin releasing factor in alcoholics one and three weeks following cessation of drinking." American Psychiatric Association 139th Annual Meeting, Washington, DC, May 13, 1986.
- Adinoff B, Rohrbaugh JW, Stapleton JM, Parasuraman R, Frowein HW, Varner JL, Lane EA, Eckardt MJ, Linnoila M. "Alcohol intoxication reduces visual sustained attention." American College of Neuropsychopharmacology, Washington, DC, December 11, 1986.
- Adinoff B, Dave JR, Roehrich L, Martin PR, George T, Eskay R, Linnoila M. "Corticotrophin-releasing hormone binding sites on RBCs in alcoholics, children at risk, and normal controls." Collegium International Neuro-Psychopharmacologicum, San Juan, Puerto Rico, December 17, 1986.
- Stapleton JM, Eckardt P, Adinoff B, Roehrich L, Bone G, Rubinow D, Mefford I, Linnoila M. "Treatment of alcoholic organic brain syndrome with the serotonin reuptake inhibitor, fluvoxamine: Relationships between neurochemical and neuropsychological responses." Research Society on Alcoholism/Committee on Problems of Drug Dependence, Philadelphia, 1987.

- Adinoff B. "SPECT following IV procaine in cocaine addiction." Thirty-first Annual Winter Conference on Brain Research. Snowbird, Utah, January 26, 1998.
- Adinoff B, Devous MD, Best S, George MS, Alexander D, Payne K. "SPECT following intravenous procaine in cocaine addiction." Advancing from the Ventral Striatum to the Extended Amygdala: Implications for Neuropsychiatry and Drug Abuse. NYAS Conference, Oct. 19, 1998.
- Adinoff B. "Recovery of the Hypothalamic-pituitary-adrenal axis with abstinence." 1999 Scientific Meeting of the Research Society on Alcoholism. Santa Barbara, CA. June 27, 1999.
- Colwell K, Edens JF, Willoughby FW, Adinoff B, Houser L. "Assessing motivation to change among substance abusers." 108th Annual Conference of the American Psychological Association. Washington, DC. August, 2000.
- Adinoff B, Krebaum S, Chandler PA, Veldhuis JD, Iranmanesh A. "Dissection of HPA axis disturbances in abstinent alcohol dependent subjects." 57th Annual Convention of the Society of Biological Psychiatry, Philadelphia, PA. Ma7 18, 2002.
- Krebaum SR, Jackley PK, Adinoff B. "The Impulsive Relapse Questionnaire: A measure of automaticity in substance dependence." 64th Annual Scientific Meeting of the College on Problems of Drug Dependence. Quebec City, Canada. June 10, 2002
- Adinoff B, Devous MD Sr, Cooper DB, Best SE, Chandler P, Harris T, Cervin CA, Cullum M. "Relationship between rCBF (by SPECT) and gambling task performance in cocaine addicted subjects and controls." 64th Annual Scientific Meeting of the College on Problems of Drug Dependence. Quebec City, Canada. June 12, 2002.
- Krebaum SR, Jackley PK, Adinoff B. "The Impulsive Relapse Questionnaire: Development and validation." 2002 Scientific Meeting of the Research Society on Alcoholism and the 11th Congress of the International Society for Biomedical Research on Alcoholism. San Francisco, CA. June 29,
- Jackley PK, Krebaum SR, Adinoff B. "The Impulsive Relapse Questionnaire (IRQ): A measure of automaticity in substance dependence." ACNP 41st Annual Meeting, Dec. 10, 2002
- Adinoff B, Devous MD Sr., Best SE, Chandler P, Harris TS, Williams M. "Pharmacologic limbic activation in abstinent cocaine-dependent subjects." ACNP 41st Annual Meeting, Dec. 10, 2002
- Adinoff B, Devous MD Sr, Williams MJ, Best SE, Zielinski T, Harris TS, Schreffler ER. "Differences in rCBF Response between Abstinent Cocaine-addicted Subjects and Healthy Controls to the 5HT3 Antagonist, Ondansetron." American College of Neuropsychopharmacology 43rd Annual Meeting. San Juan, Puerto Rico. Dec. 13, 2004.
- Adinoff B, Williams MJ, Best SE, Zielinski T, Harris TS, Schreffler ER, Devous MD Sr. "Cholinergic receptor systems in cocaine-addicted subjects: Alterations regional cerebral blood flow. American College of Neuropsychopharmacology, 44th Annual Meeting. Waikoloa, Hawaii. Dec. 12, 2005
- Adinoff B. "HPA Axis Dysregulation in Alcoholism and the Clinical Trials Network: Texas Node." Texas Research Society on Alcoholism, 16th Annual Scientific Meeting. Texas A&M University System HSC, College Station, Tx. February 16, 2006.
- Schreffler E, Adinoff B, Briggs R, Goyal A, Coleman A, Cheshkov S, Modhia S, Harris T, Devous MD Sr. "Stress, the HPA axis, and fMRI in alcoholism: Preliminary studies." Texas Research Society on Alcoholism, Texas A&M University, College Station, TX. February 17, 2006.
- Adinoff, B, Williams MJ, Best SE, Zieklinski T, Harris T, Schreffler E, Devous MD. "Cholinergic receptor systems in cocaine-addicted subjects: Alterations in regional cerebral blood flow." 68th Annual Scientific Meeting of the College on Problems of Drug Dependence. Phoenix, AZ. June 18, 2006.
- Williams MJ, Chandler PA, Best SE, Ye W, Brown MD, Adinoff B. "Dissection of hypothalamic-pituitaryadrenal axis pathology in 1-month-abstinent alcohol-dependent women: adrenocortical and pituitary glucocorticoid responsiveness." 29th Annual Meeting of the Research Society on Alcoholism. Baltimore, MD. June 26, 2006
- Field CA, Duncan J, Washington K, Adinoff B. "Association of baseline characteristics and motivation

- Meng Y, Rao U, Xiao H, North CS, Adinoff B. Neuropeptide Y (NPY) and Brain-Derived Neurotrophic Factor (BDNF) responsivity after acute stress in alcohol-dependent and control subjects. Research Society on Alcoholism, 33nd Annual Meeting. San Antonio, CA. June 2010.
- Leachman LL, Fielding SK, Shalvoy AM, Walker NR, Minhajuddin A, North CS, Rao U, Xiao H, Adinoff B. Relationship of self-reported childhood trauma to personality characteristics in alcoholdependent men. Research Society on Alcoholism, 33nd Annual Meeting. San Antonio, CA. June 2010.
- Shalvoy AM, LL Leachman, Fielding SK, Walker NR, Minhajuddin A, North CS, Rao U, Xiao H, Adinoff B. Antisocial personality characteristics and alcohol use as a predictor for cortisol reactivity to a behavioral stressor. Research Society on Alcoholism, 33nd Annual Meeting. San Antonio, CA. June 2010.
- Braud J, Devous MD, Harris TS, Adinoff B. Relationship of impulsive personality traits and orbitofrontal rCBF in cocaine-addicted and healthy control subjects. College on Problems of Drug Dependence. Scottsdale, AZ. June 13, 2010.
- Adinoff B, Harrington CR, Beswick TC, Graves M, Jacobs HT, Devous MD, Harris TS. Increased striatal activation in compulsive indoor tanners upon exposure to ultraviolet light compared to sham light. College on Problems of Drug Dependence. Scottsdale, AZ. June 17, 2010.
- Adinoff B, Harrington C, Devous M, Jacobe H, Harris T. Increased striatal activation in compulsive indoor tanners upon exposure to ultraviolet light compared to sham light. American College of Neuropsychopharmacology. Miami, FL. December 7, 2010.
- Liu P, Uh J, Devous MD, Adinoff B, Lu H. SPECT validation of pseudo-continuous arterial spin labeling MRI. International Society for Magnetic Resonance in Medicine, 19th Annual Meeting. Montreal, Canada, May 2011.
- Denton WH, Winhusen T, Walker NR, Adinoff BH. Family discord is associated with increased substance use for pregnant substance users. International Association for Relationship Research Mini-Conference on Health, Emotions, and Relationships. Tucson, AZ. October 2011.
- Braud J, Harris TS, Devous MD, Spence JS, Briggs R, Walker NR, Cullum M, Adinoff B. Neural alterations during decision-making in cocaine-addicted subjects. Metroplex Days. Dallas, TX. February 2012.
- Adinoff B. Neuroimaging in addiction: Common threads. Texas Research Society on Alcoholism, 22nd Annual Scientific Meeting. Texas A&M University System HSC, College Station, TX. February 24, 2012.
- Winhusen T, Lewis D, Adinoff B, Brigham G, Kropp F, Donovan D, Somoza E. Failure to look before leaping: The Barratt Impulsiveness Scale predicts treatment completion in cocaine-and methamphetamine-dependent patients. College on Problems of Drug Dependence. Palm Springs, CA. June 11, 2012.
- Mete M, Adinoff B, Devous MD, Spence JS. A machine learning approach for patient classification in cocaine addiction via SPECT images. College on Problems of Drug Dependence. Palm Springs, CA. June 11, 2012.
- Adinoff B, Devous MD, Williams MJ, Harris TS, Best SE, Dong H, Zielinski TA. Differences in regional cerebral blood flow response to a 5HT3 antagonist in early-and late-onset cocaine dependence. College on Problems of Drug Dependence. Palm Springs, CA. June 14, 2012.
- McHugh M, Gu H, Yang Y, Braud J, Devous M, Briggs R, Walker NR, Adinoff B, Stein E. Resting state network dynamics predict relapse in cocaine-dependent individuals. American College on Neuropsychopharmacology 51st Annual Meeting. Hollywood, FL. December 4, 2012.
- Gu H, McHugh M, Yang Y, Shope C, Braud J, Devous M, Briggs R, Walker NR, Cullum M, Stein E, Adinoff B. Resting regional cerebral blood flow to predict relapse in cocaine dependent individuals. American College on Neuropsychopharmacology 51st Annual Meeting. Hollywood, FL. December 4, 2012.

- Liu P, Adinoff B, Tamminga CA, Filbey F, Lu H. Impact of cocaine use on brain metabolism: Hypoactivity, dose dependence, and relationship to cognitive ability. Proceedings of the 21st Annual Meeting of ISMRM, Salt Lake City, Utah, USA. April 25, 2013. p.738.
- Merrick C, Adinoff B, Gu H, McHugh M, Devous MD, Briggs R, Sunderajan P, Yang Y, Stein EA. Localized functionally connected neural predictors of relapse in cocaine dependence. Texas Research Society on Alcoholism 37th Annual Meeting. San Antonio, TX. February 21, 2014.
- Merrick C, Adinoff B, Gu H, McHugh M, Devous MD, Briggs R, Sunderajan P, Yang Y, Stein EA. Localized functionally connected neural predictors of relapse in cocaine dependence. Behavior, Biology and Chemistry. San Antonio, TX. March 14-16, 2014.
- Vingren JL, Adinoff B, Duplanty AA, Budnar RG, Luk HY, Xiao H, Hill DW. Muscle glucocorticoid receptors and long-term alcohol abuse: Preliminary findings. 13th Biennial Advances in Skeletal Muscle Biology in Health and Disease Conference, Gainesville, Florida. March 2014.
- Akgun D, Sakoglu M, Mete M, Esquivel J, Adinoff B. GPU-accelerated dynamic functional connectivity analysis for functional MRI data using open CL. IEEE International Conference. Milwaukee, WI. June 2014.
- Adinoff B, Gu H, Merrick C, McHugh M, Devous M, Yang Y, Stein E. Localized and functionally connected neural predictors of relapse in cocaine dependence. College on Problems of Drug Dependence. San Juan, Puerto Rico. June 18, 2014.
- Price JL, Leonard D, Rao U, Walker R, Javors M, Xiao H, Adinoff B (2014). Ongoing stress moderates pituitary-adrenal reactivity in predicting post-treatment drinking severity. Poster presented at the 37th Annual Meeting of the Research Society of Alcoholism (RSA), Bellevue, WA (June 21-25, 2014) and Behavior, Biology, and Chemistry, San Antonio, TX (March 14-16, 2014).
- Adinoff B, Aubert PM, Harris TS, Filbey FM, Devous MD, Price JL, Jacobe HM, Seibyl J. Dopamine efflux in response to ultraviolet radiation in addicted sunbed users. American College on Neuropsychopharmacology 53rd Annual Conference. Phoenix, AZ. Dec 9, 2014.
- Rice J, Spence J, Rubia K, Harris TS, Briggs R, Devous M, Adinoff B. The anterior salience network and impulsivity in cocaine-dependent individuals. 12th Annual AMA Research Symposium-Medical Student Section. Dallas, TX. November 7, 2014.
- Wilcox CE, Ling JM, Pommy JM, Adinoff B, Bigelow RC, Mayer AR, Bogenschultz MP. Prazosin decreases striatal bold response to conditioned stress stimulus in alcohol use disorder. Research Society on Alcoholism. San Antonio, TX. June 23, 2015.
- Adinoff B, Spence J, Gu H, Rice J, Rubia K, Yang Y, Briggs R, Walker R, Stein EA. Disrupted relationship of conscientiousness to BOLD activation during error monitoring and resting state functional connectivity in cocaine-dependent and healthy control subjects. *American College on Neuropsychopharmacology* 54th Annual Conference. Hollywood, FL. Dec. 8, 2015
- Sparks H, Morrow L, Javors, M, Adinoff B. Dexamethasone suppressed neurosteroid predicts posttreatment drinking in alcohol-dependent men. Texas Research Society on Alcoholism, Dallas, TX. February 19, 2016.
- Kepinski I, Gu H, Blackledge S, Yang Y, Stein EA, Adinoff B. Amygdala and NEO impulsiveness (N5) in cocaine use disorders. Texas Research Society on Alcoholism, Dallas, TX. February 19, 2016.
- Blackledge S, Kepinski I, Yang H, Adinoff B. Effects of neuroticism and alcohol dependence on neuronal reactivity during uncertain heat threat: Implications for the default mode and executive control networks. Texas Research Society on Alcoholism, Dallas, TX. February 19, 2016.
- Wright R, Adinoff B. Bupropion misuse: A systematic review. UT Southwestern Medical Center. May 25, 2016
- Adinoff B, Blackledge S, Kepinski I, Gu H, Yang Y, Stein EA. Amygdala volume, resting state functional connectivity, and NEO Impulsiveness (N5) in cocaine use disorder. American College on Neuropsychopharmacology 55th Annual Conference. Hollywood, CA. Dec. 6, 2016.
- Becker JE., Price JL, Kandil E, Shaw MA, Suris A, Kroener S, Brown ES, Adinoff B. Efficacy of lidocaine in disrupting cocaine-cue induced memory reconsolidation. Behavior, Biology, and

Page 33

- Chemistry: Translational Research in Addiction Conference, San Antonio, TX. March 4, 2017

 Price JL, Acevedo S, Javors MA, Walker R, Nixon SJ, Adinoff B. CRHR1 genotype differentially moderates HPA axis in healthy controls and alcohol-dependent men. 40th Annual Meeting of the Research Society on Alcoholism (RSA), Denver, CO. June 24-28, 2017.
- Price JL, Frazier IR, Javors MA, Walker R, Nixon SJ, Adinoff B. Differences in HPA function between Black and White alcohol-dependent men. Poster presented at the University of Florida College of Medicine Celebration of Research, Gainesville, FL (February 27, 2017), the 4th Annual International Congress on Alcoholism and Stress, Volterra, Italy (May 9-12, 2017), and the 40th Annual Meeting of the Research Society on Alcoholism (RSA), Denver, CO (June 24-28, 2017). Finalist for the Enoch Gordis Research Award.
- Westover A, Adinoff B, Halm E, Nakonezny P. Risk of stimulant use disorder and mortality among incident users in the Veterans Administration. College on Problems in Drug Dependence 79th Annual Scientific Conference. Montreal, Canada. June 22, 2017.
- Yu J-C, Fiore VF, Spence JS, Briggs RW, Braud J, Adinoff B, Gu X. Multiple system dysfunction in addiction: evidence from model-based fMRI. 47th annual meeting of Society for Neuroscience, Washington, DC. November, 2017.
- Sakoglu U, De Leon J, Huerta C, Galla M, M Mutlu, Adinoff B. Classification of cocaine addiction using Hilbert-Curve Ordering of fMRI activations. International Society for Magnetic Resonance in Medicine (ISMRM) Workshop on Machine Learning. Pacific Grove, CA. March 14-18, 2018.
- Becker JE, Price JL, David Leonard D, Suris A, Kandil E, Meredith Shaw M, Sven Kroener S, Brown ES, Adinoff B. The Efficacy of Lidocaine in Disrupting Cocaine Cue-Induced Memory Reconsolidation." CPDD 80th Annual Scientific Meeting, San Diego, CA. June 14, 2018.

Community Presentations:

- "The Neurobiology of Drug and Alcohol Addiction." In *Mitigation How to Explain Behavior*, The Center for American and International Law. Plano, TX. April 30, 2005.
- "What We're Learning About the Neuroscience of Addiction". Reinvesting in Justice: What Comes Next? Center for Court Innovation. Dallas, TX. November 12, 2015.
- Speaker, Panel on "Cops, Docs, and Clergy- War on Drugs Program," Republican Liberty Caucus of Texas Convention. Austin, TX. February 12, 2016.
- Speaker, Panel on "Cops, Docs, and Clergy- War on Drugs Program." Huston-Tillotson University. Austin, TX. February 12, 2016.
- Speaker, Panel on Medical Marijuana, Pro Athletes Pro Cannabis, Ft. Worth, TX. April 21, 2017.
 Speaker, Panel on "Cannabis and Chronic Traumatic Encephalopathy," Southwest Cannabis Conference and Expo, Ft. Worth, TX. April 22, 2017.
- Speaker, Veterans Cannabis Forum, American Legion Post 453, Dallas, TX. May 26, 2018
 Speaker, Panel on "Medical Cannabis: What does the research tell us?" Texas Marijuana Policy Conference, Austin, TX. August 11, 2018.
- Speaker, Panel on "PTSD, Pain and Cannabis." Online Texas Veteran Cannabis Conference. Oct 17, 2020.
- Speaker, Panel on "Texas Veterans: Service-Related Injuries and Cannabis Treatment." Texas Marijuana Policy Conference 2020 (Virtual). Nov 11, 2020.
- Speaker, Panel on "Remembering the Patients." Yes We Cannabis Rhode Island. Facebook Live Stream. March 14, 2022.
- Speaker, <u>Panel</u> on "Brittney Griner's Imprisonment in the Context of Cannabis Prohibition in the US & Russia." Doctors for Cannabis Regulation webinar. Sept 14, 2022.
- Speaker, <u>Panel</u> on "Understanding the medical science behind substance misuse, addiction, and recovery." Denver City Council. Denver, CO. Feb 1, 2023.
- Interview (virtual), VAC Roundtable #51. Veterans Action Council. Feb 3, 2023.

USCA Case #24-1365 Document #2100970 Filed: 02/17/2025 Page 106 of 214

> Curriculum Vitae Bryon H. Adinoff

Page 34

Speaker, Panel on "Cannabis Law Reform Leading the Way Towards More Effective Drug Control and the Attainment of the [UN] Sustainable Development Goals." Chair: Myrtle Clark. UN Commission on Narcotic Drugs (CND) #66. Vienna, Austria. March 15, 2023.

Podcasts

- <u>Psychedelic Science 2023: Doctors for Cannabis Regulation</u>. Cannabis Radio.com. July 11, 2023
- Psychedelica Lex with Gary Smith (Part 1, 2, 3). Nov 27, 2020

 - o Part 1 o Part 2
 - o Part 3

DAVID L. NATHAN, MD, DFAPA

601 Ewing Street, Suite C-10 Princeton, New Jersey 08540 www.nathanmd.com mail@nathanmd.com Phone: 609-688-0400 Fax: 609-688-0401

PLACE OF BIRTH

Philadelphia, Pennsylvania

EDUCATION

MD, University of Pennsylvania School of Medicine, Philadelphia, PA
 AB in biology, magna cum laude, Princeton University, Princeton, NJ

POSTGRADUATE TRAINING

1994-1998 Resident, Psychiatry, McLean Hospital, Harvard Medical School, Belmont, MA

ACADEMIC APPOINTMENTS

2010-	Clinical Associate Professor, Department of Psychiatry, Rutgers Robert Wood Johnson Medical School (RWJMS), Piscataway, NJ	
2000-2010	Clinical Assistant Professor, Department of Psychiatry, RWJMS, Piscataway, NJ	
2000-	Community Fellow, Mathey College, Princeton University, Princeton, NJ	
1999-2000	Clinical Instructor, Department of Psychiatry, RWJMS, Piscataway, NJ	
1994-1998	Clinical Fellow, Psychiatry, Harvard Medical School, Boston, MA	

HOSPITAL APPOINTMENTS

2008-	Chairman, Continuing Medical Education Committee, Penn Medicine Princeton Health (PMPH, formerly Princeton HealthCare System [PHCS]), Princeton, NJ
2022-	Senior Attending Staff, PMPH, Princeton, NJ
2000-2022	Active/Attending Staff, PMPH, Princeton, NJ
1998-2000	Associate Staff, PHCS, Princeton, NJ
1998-1999	Courtesy Attending Staff, Carrier Foundation, Belle Mead, NJ

EMPLOYMENT HISTORY

2018-2020 Chief Medical Advisor, 4Front Ventures. Provided information and guidance on evidence-based cannabis science and medicine to company leadership and employees at a multistate cannabis cultivator and retailer. Wrote educational materials for physicians, patients, staff and

David L. Nathan, MD, DFAPA

the public. Identified and recruited experts in the scientific community	and wrote and edited
content for state license applications.	

- 2016- Consultant, Princeton Psychiatry and Consulting, LLC, Princeton, NJ. Serve as an expert medical consultant on drug policy-related topics for government, businesses, investors, education companies and policy groups. Speak at cannabis-related conferences and other events. Design cannabis labeling and packaging. Assist with regulatory compliance and medical issues with completion of state license applications.
- 2008- Director of Continuing Medical Education, PMPH (formerly PHCS), Princeton, NJ. Provide all leadership and supervision in connection with the offering, communication and management of educational programs to physicians on the PMPH Medical Staff, while meeting all guidelines and standards of the Accreditation Council for Continuing Medical Education and the American Medical Association.
- 1999- Director of Professional Education, Department of Psychiatry, PMPH (formerly PHCS), Princeton, NJ. Organize grand rounds and moderate case conferences for psychiatrists, psychologists, nurses and social workers.
- 1998- Private Practice Psychiatrist. Princeton Psychiatry and Consulting, LLC, Princeton, NJ. Provide outpatient psychiatric care to adults in the community, using the modalities of psychotherapy and psychopharmacology.
- 1998-1999 Consult-Liaison Psychiatrist, The Medical Center at Princeton, Princeton, NJ. Completed all routine psychiatric consultations on medical and surgical floors. Served as liaison to medical and nursing staff.
- 1998-1999 Evaluating Psychiatrist, Princeton House Behavioral Health, Princeton, NJ. Assessed and monitored patients in the geriatric, substance abuse and general adult partial hospital programs of Princeton House.

LICENSURE AND CERTIFICATION

1999-	American Board of Psychiatry and Neurology - Board Certification in Psychiatry
2022-	Pennsylvania Board of Registration in Medicine - inactive license
2016-2022	Pennsylvania Board of Registration in Medicine - active license
1998-	New Jersey State Board of Medical Examiners - full license
1996-1998	Massachusetts Board of Registration in Medicine - full license
1992-1995	United States Medical Licensing Examination - Steps 1, 2 and 3

AWARDS AND HONORS

2022	NJ.com: 22 People and Places to watch in the NJ Cannabis Space in 2022
2021	Insider NJ: Top 100 influential voices in the cannabis debate (insidernj.com)
2021	NJ.com: 21 People and Places to watch in the NJ Cannabis Space in 2021
2019	Insider NJ: Top 100 influential voices in the cannabis debate (insidernj.com)
2018	Honorary Board of ICANNA: International Institute for Cannabinoids, Slovenia
2012	Distinguished Fellow of the American Psychiatric Association (DFAPA)
2010	Fellow of the American Psychiatric Association (FAPA)
2007	Odesser Award for Outstanding Contribution to Judaic Numismatics and Exonumia
1990	High honors in biology, Princeton University

3

David L. Nathan, MD, DFAPA

Sigma Xi Science Honor Society, selected by members of Princeton's faculty
 Charles M. Cannon Memorial Prize for best thesis presentation, Princeton University

Department of Biology

PROFESSIONAL SOCIETIES AND PATIENT ADVOCACY GROUPS

2023-	Co-founder and Past President, Doctors for Drug Policy Reform (D4DPR)
2021-2023	Founder and Past President, Doctors for Cannabis Regulation (DFCR)
2021-	Founding board member, NJ-NORML
2015-2021	Founder and Board President, Doctors for Cannabis Regulation (DFCR)
2014-	Founding steering committee member, New Jersey United for Marijuana Reform
2012-	Distinguished Fellow, American Psychiatric Association (APA)
2008-	Member, Medical Society of New Jersey (MSNJ)
2003-	Physician Advisor, New Jersey State Chapter of the Depression and Bipolar Support Alliance (DBSA-NJ)
1998-	Professional Member, National Alliance for the Mentally III (NAMI)
1998-	Member, New Jersey Psychiatric Association (NJPA)
2020	Steering committee member, NJ CAN 2020, a cannabis legalization campaign
2010-2012	Fellow, APA
1994-2010	General Member, APA
1994-1998	Member, Massachusetts Psychiatric Society (MPS)

SELF REPORT OF TEACHING

2008-	Director of Continuing Medical Education, Penn Medicine Princeton Health, Princeton, NJ. Provide leadership and supervision in connection with the offering, communication and management of educational programs to physicians on the PMPH Medical Staff, while meeting all guidelines and standards of the Accreditation Council for Continuing Medical Education and the American Medical Association.
2004-	Director of Professional Education, Department of Psychiatry, Penn Medicine Princeton Health. Organize grand rounds and moderate case conferences for psychiatrists, nurses and social workers. Supervise a second monthly grand rounds run by a psychologist.
2003-2005	Member, Medical Advisory Board of the Princeton Fitness & Wellness Center.
1999-2004	CME Course Director for Psychiatry, Department of Psychiatry, Medical Center at Princeton Organized grand rounds for the department of psychiatry and created a case conference for psychiatrists.
1999-2008	Member, CME Committee, Princeton HealthCare System.
2007-2012	Member, Ethics Consultation Subcommittee of the Biomedical Ethics Committee, Princeton HealthCare System.
1999-2012	Member, Biomedical Ethics Committee, Princeton HealthCare System.
1998-1999	Clinical Instructor, The Medical Center at Princeton, Robert Wood Johnson Medical School. Teaching third and fourth year medical students completing their psychiatry rotations on the Consult-Liaison Service at the Medical Center at Princeton.

David L.	Nathan,	MD,	DFAPA
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1997-1998	Chief Resident, Bipolar and Psychotic Disorders Program, McLean Hospital. Supervised sixteen second year residents from the MGH/McLean Residency Program. Organized weekly case conferences with visiting consultants on the inpatient unit. Created and organized weekly outpatient clinic for four third year residents, including monthly case conferences.
1997-1998	Preceptor, Core Clerkship in Psychiatry, Harvard Medical School. Supervised third and fourth year medical students completing their psychiatry rotations at McLean Hospital.
1995-1998	Tutor, Psychopathology & Introduction to Clinical Psychiatry, Harvard Medical School. Semester-long course for second year medical students to learn about psychiatric interviewing and the mental status examination.
1993-1994	Coordinator, 1994 Penn Med Ed Software Project, University of Pennsylvania School of Medicine. Conceived and facilitated work on programs in human development, embryology and endocrine physiology by medical students and faculty.
1992-1993	Founder and coordinator, 1993 Penn Med Ed Software Project, University of Pennsylvania School of Medicine. Selected and supervised eight medical students to complete five computer programs.
1991-1992	Conceived and designed Histological Anatomy Review Program; selected and supervised eight medical students' completion of this and Gross Anatomy Review Program.
1992	Exhibitor, Symposium: Computers in Health Care Education, Health Sciences Library Consortium & Thomas Jefferson University, Philadelphia, PA.
1992	Exhibitor, Symposium: Computers in Medical Education, University of Pennsylvania, Philadelphia, PA.
1991	Conceived, designed and illustrated Gross Anatomy Review Program, an animated computer dissection and tutorial.

SELECTED PUBLICATIONS

Editorial Boards:

2021-	Member, Editorial Board, Medical Cannabinoid Journal
2020-	Member, Editorial Board, Cannabis Science and Technology
2019-2023	Member, Editorial Board, American Journal of Endocannabinoid Medicine

Journal Articles:

- Nathan, D.L., Oepen, G., Havens, L. and McClung, E.D. "Two Views of a Delusion." Harvard Rev Psychiatry 1998; 6: 97-104.
- Nathan, D.L. "A 'New' Proto-Cuneiform Tablet." Cuneiform Digital Library Bulletin 2003:4. March 2003.
- Nathan, D.L. Review of The Midnight Disease. American Journal of Psychiatry. October 2004; 161: 1937-
- Nathan, D.L. "A Hebrew Letter on the New World's First Coins?" The Shekel. January-February 2006.
- Nathan, D.L. and Crafton, D. "The Making and Remaking of Gertie." Animation 8:1. March 2013. pp. 23-46.
- Nathan, D.L. "That summer evening, long ago, a-sitting on a gate." The Knight Letter. January 2014. pp. 23-26.
- Nathan, D.L., Elders, J., Clark, H.W. "The Physicians' Case for Marijuana Legalization." American Journal of Public Health 107:11. November 2017. pp. 1746-1747.
- Nathan, D.L. "Setting the Standard for Cannabis Labeling: Introducing the Universal Cannabis Product Symbol and the Universal Cannabis Information Label." Cannabis Science and Technology 3:6, August 2020. Pp. 44-52.

- Nathan, D.L. and Nathan, E. "Why All Legalized U.S. Jurisdictions Should (and Probably Will) Adopt the International Intoxicating Cannabis Product Symbol (IICPS)." Cannabis Science and Technology 5:1, November 2021.
- Nathan, D.L. "Creating a Symbol of Best Practices in Cannabis Regulatory Standards." Cannabis & Tech Today 5:3, March 2024.

News/Magazine Articles and Interviews:

- "Find ways to work through those holiday or winter blues." Princeton Packet. December 18, 1998. p. 23A.
- "Depression Guide: You're Not Alone." Barron's. September 3, 2001. pp. 34-35.
- "Try to remember the kind of September ... " Princeton Packet. September 21, 2001.
- "Shedding Light And Darkness." Barron's. March 4, 2002.
- "Trouble at the Office." Barron's. September 4, 2006. p. 36.
- "This is Your Brain on Money." Barron's. September 3, 2007. p. 40.
- "A Doctor's Case for Legal Pot." Wall Street Journal. January 15, 2010. p. 21.
- "Matter Over Mind: Psychiatrists and their Pills." Barron's. July 5, 2010. p. 33.
- "Is It High Time? Fresh looks at marijuana." Barron's. March 7, 2011. pp. 30-31.
- "Why Marijuana Should Be Legal for Adults." CNN.com. January 9, 2013. Featured Op-Ed.
- "Calls to Legalize Pot Are Gaining America's Support." CNN.com. January 16, 2013. Featured Op-Ed.
- "How to Regulate Pot When It's Legal." CNN.com. August 26, 2013. Featured Op-Ed.
- "Fighting Marijuana... Or Reality?" CNN.com. September 11, 2013. Featured Op-Ed.
- "Where It All Began: Research sparks quest to find Princeton's Unknown Player." Princeton Alumni Weekly. October 22, 2014. p. 15.
- Dozens of articles and interviews since 2015 on cannabis legalization and general drug policy reform in a variety of media outlets, including CNN, The New York Times, ESPN, Washington Post, Denver Post, San Francisco Chronicle, Las Vegas Review-Journal, Providence Journal, The Guardian, Huffington Post, MedPage Today, MD Magazine, Leafly, The Cannabist, NBC 4 New York, NBC 3 Las Vegas, CBS 3 Philadelphia, Fox 29 Philadelphia, NJTV News, WKXW 101.5 FM Trenton, KFNX 1100 AM Phoenix, WIP 1210 AM Philadelphia and other outlets.

Books and Other Monographs:

Web Repair in Several Species of Orb Weaving Spiders [Senior Thesis]. Princeton, NJ: Princeton University, 1990. 67 pp.

The Book of Nathan: Memoirs of a Nineteenth Century Romanian Immigrant. Princeton, NJ, 2006. 128 pp.

Medical Education Software:

- Creator, Designer and Illustrator, Gross Anatomy Review Program, a computerized dissection, atlas, review, and self-test, University of Pennsylvania School of Medicine, 1991-3.
- Creator and Designer, Histological Anatomy Review Program, a computerized atlas, review, and self-test, University of Pennsylvania School of Medicine, 1992-3.
- Creator, Designer and Animator, Basic Embryology Review Program, an animated atlas and review of prenatal development, University of Pennsylvania School of Medicine, 1994.
- Creator and Designer, Human Development Along a Continuum, a review of human psychological and physiological development along a continuum, University of Pennsylvania School of Medicine, 1994.

David L. Nathan, MD, DFAPA

6

Creator and Designer, Advanced Teaching Tool for Introductory Endocrinology, a review of endocrinological physiology, pathology, and pathophysiology, University of Pennsylvania School of Medicine, 1994.

Film/Theater:

Executive Producer, Gertie, a reconstruction of Winsor McCay's 1914 vaudeville stage performance and restoration of his animated film. Creator and animator for the Gertie Project beginning in 2003, and one of three scholars who served as executive producers. World premiere at the Annecy Film Festival, France, June 16, 2018.

Other Publications:

Graphics Editor, American Journal of Ethics and Medicine, 1990-1991.

Theme Editor, Scope, the University of Pennsylvania School of Medicine's Annual, 1994.

Editor, Poor David's Almanac for the Year 2006, application for the Palm OS, December 2005.

Editor, Poor David's Almanac for the Year 2007, application for the Palm OS, December 2006.

Editor, Poor David's Almanac for the Year 2008, application for the Palm OS, December 2007.

SELECTED PRESENTATIONS

Lectures and Seminars:

- "Management of Psychosis." Lecture to residents, Robert Wood Johnson Medical School, December 17, 1998.
- "Update on Antidepressants." Grand Rounds, Department of Medicine, Medical Center at Princeton, February 2, 1999.
- "Two Views of a Delusion." Paper Presentation, I Department of Psychiatry, Medical University of Warsaw, Poland, July 6, 1999.
- "Management of the Paranoid Patient." Lecture to residents, Robert Wood Johnson Medical School, October 14, 1999.
- "Psychiatric Emergencies." Lecture to residents, Medical Center at Princeton, August 25, 1999/July 25, 2001.
- "Acute Psychosis." Lecture to residents, Medical Center at Princeton, Several years since July 12, 2000.
- "Trauma and Psychiatry after September 11th." Lecture to faculty fellows at Princeton University, November 28, 2001.
- "Ask the Doctor." Seminars with members of DBSA New Jersey, periodically since 2003.
- "Alcoholism." Lecture to residents, Medical Center at Princeton, February 5, 2003.
- "Origins of Animation." Lecture to faculty fellows at Princeton University, February 25, 2003.
- "Depression in Adults." Grand Rounds, Department of Medicine, University Medical Center at Princeton, June 15, 2004.
- "Introduction to Psychiatry." Lecture to public at Princeton Fitness and Wellness Center, November 15, 2004.
- "Meteorites: Science or Cosmic Vandalism?" Lecture to faculty fellows at Princeton University, February 9, 2005.
- "A Psychiatrist's Perspective on Depression." Lecture at symposium Mental Illness as a Spiritual Journey. Princeton Theological Seminary, April 18, 2006.
- "America's History in Coins." Lecture to faculty fellows at Princeton University, October 17, 2006.

David L. Nathan, MD, DFAPA

7

- "Art and Science of Psychiatric Diagnosis."
 - 1. Grand Rounds, Department of Psychiatry, UMDNJ Camden, October 30, 2007.
 - 2. Lecture to Princeton Independent Consultants at Nassau Club, October 20, 2008.
 - 3. Grand Rounds, Department of Psychiatry, Princeton House, January 14, 2009.
 - 4. Lecture to faculty fellows at Princeton University, April 22, 2009
 - 5. Keynote Address at DBSA NJ Annual Conference, May 8, 2010.
 - Grand Rounds, Department of Medicine, University Medical Center at Princeton, December 14, 2010.
- "Cannabis." Lecture to faculty fellows at Princeton University, November 17, 2010.
- "New Directions New Jersey: A Public Safety and Health Approach to Drug Policy." Panel Discussion for Drug Policy Alliance, March 19, 2011.
- "2011 Update on Psychiatric Medications." Lecture to lay public at NAMI Mercer Harvest of Hope Conference, October 1, 2011.
- "2011 Update on Psychotropics." Grand Rounds, Department of Medicine, University Medical Center at Princeton, February 21, 2012.
- "2012 Update on Psychiatric Medications." Lecture to lay public at NAMI Mercer Harvest of Hope Conference, October 6, 2012.
- "Ethics, Medicine, and Mental Health Treatment." Lecture, Princeton Theological Seminary, October 8, 2012.
- "Bill to Tax and Regulate Marijuana Like Alcohol." Press Conference, Pennsylvania State Capitol, February
 11, 2013.
- "Marijuana and Legalization: What Clinicians Need to Know." Grand Rounds, Department of Psychiatry, Princeton House, April 8, 2013.
- "2013 Update on Psychiatric Medications." Lecture to lay public at NAMI Mercer Harvest of Hope Conference, October 5, 2013.
- "Marijuana and Legalization: What Clinicians Need to Know." Grand Rounds at McCosh Infirmary, Princeton University. November 5, 2013.
- "So You're Thinking about Medical School." Lecture to Princeton University pre-meds. November 6, 2013.
- "Stressed or Sick: Distinguishing Psychiatric Disorders from Everyday Problems." Lecture to faculty fellows at Princeton University, November 20, 2013.
- "A Doctor's Perspective on Marijuana Legalization." Lecture at Windrows, Plainsboro, NJ, March 5, 2014. "Schizophrenia." Lecture to NAMI Mercer, April 15, 2014.
- "Medications for Anxiety and Depression." Lecture to staff at Longyearbyen Sykehuset, Longyearbyen, Svalbard, August 21, 2014.
- Dozens of lectures and seminars since 2015 on cannabis legalization and regulation in a variety of settings, including the International Drug Policy Reform Conference, Policy Committee of the Medical Society of New Jersey, CannMed 2017 at Harvard Medical School, Princeton University, Rider University symposium on cannabis policy, Rutgers University symposium on cannabis policy, Southwest Cannabis Conference, Cannabis Business Executives Conference and other venues.

Testimony in State Legislatures:

Testimony on marijuana legalization; Senate Judiciary Committee, New Jersey State Legislature, Trenton, NJ, November 16, 2015.

- Testimony on An Act Concerning the Regulation and Taxation of the Retail Sale and Cultivation of Marijuana (HB 5314); Public Health Committee, Connecticut General Assembly, Hartford, CT, March 7, 2017.
- Testimony on Cannabis Regulation, Control and Taxation Act (H 5555); House Judiciary Committee, State of Rhode Island General Assembly, Providence, RI, April 11, 2017.
- Written testimony on the Delaware Marijuana Control Act (HB 110); House Revenue and Finance Committee, Delaware General Assembly, May 10, 2017.
- Testimony on Cannabis Legalization Bill (S 2195); New Jersey State Legislature, Trenton, NJ, June 19, 2017.
- Testimony on Cannabis Regulation and Taxation Act (SB 316, HB 2353); Illinois General Assembly, Chicago, IL, January 22, 2018.
- Testimony on marijuana legalization; Oversight, Reform and Federal Relations Committee, New Jersey State Legislature, Trenton, NJ, March 5, 2018.
- Testimony on the reclassification of marijuana; New Jersey Division of Consumer Affairs, Trenton, NJ, April 24, 2018.
- Testimony on cannabis legalization; Joint Standing Committees on Codes, Health, Governmental Operations, and Alcoholism and Drug Abuse, New York State Assembly, New York, NY, October 16, 2018.
- Testimony on An Act Relating to the Regulation of Cannabis (S 54); Senate Judiciary Committee, Vermont General Assembly, January 31, 2019.
- Written Testimony on New Jersey Cannabis Regulatory and Expungement Aid Modernization Act (S 2703 / A 4497); Senate Judiciary Committee and Assembly Judiciary Committee, New Jersey State Legislature, Trenton, NJ, March 18, 2019.
- Testimony on marijuana legalization, House Finance Committee; Pennsylvania General Assembly, Harrisburg, PA, June 10, 2019.
- Testimony on An Act Relating to the Regulation of Cannabis (S 54); House Health Care Committee, Vermont General Assembly, January 24, 2020.
- Written Testimony on An Act Concerning the Adult Use of Cannabis (SB 16); Judiciary Committee, Connecticut General Assembly, Hartford, CT, March 3, 2020.
- Testimony on enabling legislation for marijuana legalization; Assembly Oversight, Reform and Federal Relations Committee, New Jersey State Legislature, Trenton, NJ, November 9, 2020.
- Testimony on the New Jersey Cannabis Regulatory, Enforcement Assistance, and Marketplace Modernization Act (A21); Assembly Appropriations Committee, New Jersey State Legislature, Trenton, NJ, November 19, 2020.
- Testimony on the prevention of non-medical underage cannabis use; Senate Judiciary Committee, New Jersey State Legislature, Trenton, NJ, February 15, 2021.
- Testimony on cannabis legalization (HB 150); House Health & Human Development Committee, Delaware General Assembly, March 24, 2021.
- Testimony on marijuana regulation (HB 305); House Health & Human Development Committee, Delaware General Assembly, January 26, 2022.
- Testimony supporting cannabis labeling requirements (LD2147); Joint Standing Committee of Veterans and Legal Affairs, Maine State Legislature, January 24, 2024
- Testimony on cannabis regulation (SB 3335, HD1); House Committee on Consumer Protection and Commerce, Hawai'i State Legislature, March 18-20, 2024.

David L. Nathan, MD, DFAPA

Testimony in United States Congress:

Testimony on marijuana legalization, "Marijuana Laws in America: Racial Justice and the Need for Reform." Subcommittee on Crime, Terrorism and Homeland Security; US House Judiciary Committee. United States House of Representatives, Washington, DC, July 10, 2019.

Date Prepared: April 30, 2024

Devan Maurice Dupuis & Nicholas Barreto 62 Washington street A10 Haverhill, MA, 01832 devandupuis@gmail.com [781-351-3166]

June, 20, 2024

Drug Enforcement Administration Attn: Administrator 8701 Morrissette Drive Springfield, Virginia 22152

Subject: Request for Hearing and Waiver -

Document Type: Proposed Rule Document Citation: 89 FR 44597 Page: 44597-44622 (26 pages)

CFR: 21 CFR 1308

Agency/Docket Numbers: Docket No. DEA-1362

A.G. Order No.: 5931-2024 Document Number: 2024-11137

To Whom It May Concern,

We are writing to formally request a hearing and submit a waiver in connection with the regulatory proceedings referenced above. We assert our position on the matters of fact and law as outlined below and seek the opportunity to present our case before the appropriate authorities.

Statement of Position:

- Matters of Fact:
- The proposed rescheduling of cannabis from Schedule I to Schedule III does not adequately address the systemic issues and historical injustices associated with its classification.

- The continued scheduling of cannabis, even at Schedule III, unfairly benefits pharmaceutical companies, limiting access for patients and the general public who could benefit from its therapeutic properties.
- The LaGuardia Committee Report (1944) concluded that marijuana is not addictive, does not lead to the use of harder drugs, and poses no significant social danger. This report challenges the stigma associated with cannabis use. This study indicated that cannabis does not meet the criteria for Schedule I or even Schedule III substances, citing its medical benefits and low potential for abuse.
- The Shafer Commission Report (1972) recommended the decriminalization of personal cannabis use, highlighting the disproportionately harsh penalties imposed under current laws. This study indicated that cannabis does not meet the criteria for Schedule I or even Schedule III substances, citing its medical benefits and low potential for abuse.
- The Medical College of Virginia Study (1974) found that THC, a component of cannabis, could shrink tumors and effectively combat cancer cells. This groundbreaking research underscores the potential therapeutic benefits of cannabis.
- The Institute of Medicine (IOM) Report (1982) emphasized the need for further research into cannabis's medical uses and its potential therapeutic benefits, advocating for a more scientific approach to cannabis policy.
- DEA Administrative Law Judge Francis Young's Ruling (1988) concluded that "Marijuana, in its natural form, is one of the safest therapeutically active substances known to man," recommending its reclassification to facilitate medical use. This ruling challenges the current classification of cannabis as a Schedule I substance.
- The Institute of Medicine Report (1999) acknowledged the medical benefits of cannabis and advocated for continued research to explore its therapeutic potential.

- The World Health Organization (WHO) Recommendations (2019) suggested the international rescheduling of cannabis and its derivatives due to medical benefits and lower risk profiles compared to other Schedule I substances, highlighting global recognition of cannabis's medicinal value.
- Nixon Administration: In the 1970s, President Richard Nixon commissioned studies on cannabis, including the Medical College of Virginia Study, which found promising medical uses for THC. Despite these findings, Nixon dismissed the research and escalated the War on Drugs, perpetuating misinformation about cannabis.
- Reagan Administration: During the 1980s, the Reagan administration ignored recommendations from the Institute of Medicine and other scientific bodies advocating for further research into cannabis's medical benefits. Policies during this era reinforced strict anti-cannabis laws and hindered scientific progress.

2. Matters of Law:

- These historical and scientific findings challenge the basis for current cannabis scheduling under the Controlled Substances Act (21 CFR 1308). The evidence presented supports the argument for reconsidering the scheduling of cannabis to reflect its therapeutic potential and societal impact accurately.

We believe that a hearing is necessary to ensure a fair and thorough examination of these issues. We respectfully request that the DEA schedule a hearing at the earliest convenience to address these matters.

For informational purposes, We are also sending courtesy copies of this request for hearing and waiver to the following addresses:

- Drug Enforcement Administration
 Attn: Hearing Clerk/OALJ
 8701 Morrissette Drive
 Springfield, Virginia 22152
- Drug Enforcement Administration Attn: DEA Federal Register Representative/DPW

8701 Morrissette Drive Springfield, Virginia 22152

Thank you for your attention to this request. We look forward to your response and the opportunity to present our case.

Sincerely,

Nicholas Barreto and Devan Dupuis



6-20-2024

Drug Enforcement Administration, Attn: Hearing Clerk/OALJ 8701 Morrissette Drive Springfield, Virginia 22152

Subject: Request for Hearing

Dear Sir:

The undersigned, Lori Robinson, hereby requests a hearing in the matter of: Docket No. DEA-136. Transferring marijuana from Schedule I of the Controlled Substances Act ("CSA") to Schedule III of the CSA. I am writing to register my opposition to the recommendation to move marijuana from Schedule 1 to Schedule III of the Controlled Substances Act.

My name is Lori Robinson, and I have a particular interest in rescheduling marijuana because of the egregious harm it has caused my family in 2009 when my oldest son, Shane Ryan Robinson, began using medicinal marijuana for what he believed would provide pain relief (as he was intolerant of prescription pain medication after surgery following a wakeboarding accident) but instead suffered a psychotic break from using THC marijuana, As a direct result of the detrimental brain assault to my always healthy, vibrant and accomplished son from THC marijuana which triggered cannabis-inducedpsychosis ending in Shane's unfathomable suicide in 2012, I began networking with physicians, neuroscientists, and pharmacologists after finding many other parents across the country who had also suffered similar tragedies with their teens and young adult children from this drug, in 2016, I formed one of the first parent activist organizations Moms Strong, to educate about marijuana harms. I believe, as do the many parents who I've networked over the years since, our children are the canaries in the coal mine.

In 1996, CA became the first state in the nation to approve by popular vote medical marijuana which allowed the marijuana industry to circumvent the FDA regulatory process how all other bona fide medicines are approved. For a drug to be approved by the FDA, it must be proven in clinical trials to be safe, effective for its intended use, and manufactured with uniform quality and potency. This has not been proven with smoked, vaped or edible forms of THC marijuana. Currently, states are regulating non-FDA-approved-cannabis products with no safety warnings!! And our children, teens and young adults, are particularly vulnerable to addiction and mental health disorders at this age.

The Moms Strong community strongly argues 21st century marijuana and all its byproducts are not harmless, yet many Americans believe this falsehood. Our children and our families are suffering unimaginable horrors caused by this drug. There is abundant scientific evidence, besides the sad, personal stories found on the website, the reality is marijuana is a potent and addictive substance with the potential to cause significant, irreparable harm. A new study published in the journal *Psychological Medicine* has found that teens who use cannabis are at an **elevenfold higher risk** of developing a psychotic disorder compared to those who do not use the drug. This study underscores the potential mental health risks associated with cannabis use among adolescents.

As a grandmother to a one-year-old grandson, I remain terrified at the soaring number of pediatric THC poisonings throughout the country. A study published Jan 2023 in the journal Amer Academy of Pediatrics highlights the increasing frequency and potential for acute toxicity of pediatric cannabis ingestions associated with widespread legalization. Seventy percent of the cases in this study were reported to have central nervous system depression which in some cases required intubation as the child's breathing stopped.

Please allow American families harmed by marijuana to be heard and represented in considering the risks of rescheduling marijuana. Our communities are naïve and completely unaware about cannabis-use-disorders (cannabis-induced-psychosis, cannabis-induced-schizophrenia, cannabinoid hyperemesis syndrome), cannabis associated cardiovascular events. Cannabis is the most common illicit substance detected in suicide victims' toxicology tests. The American Trucking Associations group opposes federal effort to reclassify marijuana due to considerable negative consequences for highway and safety-sensitive industries

I encourage you to follow the science and public health evidence on this issue and keep marijuana in Schedule I.

All notice to be sent pursuant to the proceeding should be addressed to:
Lori Robinson M.S.,R.D.
638 Lindero Canyon Rd, #403
Oak Park, CA 91377

Yours truly, Kokinson

Founder, Parent. Grandparent, Advocate

Moms Strong
638 Lindero Canyon Rd. #403 Oak Park, CA 91377
Momsstrong.org niomsstronginfo a.gmail.com
805-300-2447

Office of the Chair Washington, DC 20594

June 20, 2024

The Honorable Anne Milgram Administrator Drug Enforcement Administration 8701 Morrissette Dr. Springfield, VA 22152

Re: Docket Number DEA-1362



Filed: 02/17/2025

9001 26 AM 9: 15

Dear Administrator Milgram:

As chair of the National Transportation Safety Board (NTSB), I am aware that the US Drug Enforcement Administration (DEA) has received one or more hearing requests that include transportation safety topics pertaining to the DEA's notice of proposed rulemaking, "Schedules of Controlled Substances: Rescheduling of Marijuana," published at 89 Federal Register 44597 on May 21, 2024.

The NTSB will provide formal comments on the DEA-proposed rule next month. I write now to express my support for an in-person hearing to examine the facts and expert opinions regarding the effects of the proposed rescheduling action on transportation safety. If you decide to hold such a hearing, as I hope you will, I will support NTSB participation, and anticipate filing a written notice of intent to participate pursuant to 21 Code of Federal Regulations (CFR) 1308.44(b).

I am deeply concerned that the proposed rule would prevent testing transportation employees in safety-sensitive positions (under 49 CFR Part 40) and air traffic controllers (under federal workplace-drug testing procedures) for marijuana use. Currently, such testing is authorized for only Schedule I and II controlled substances. More broadly, the complex transportation safety implications of marijuana rescheduling have a potential to affect everyone who interacts with transportation systems and infrastructure, from vehicle operators and passengers to pedestrians and bystanders.

2

Thank you for considering the vital public health issue of transportation safety as you evaluate hearing requests.

Sincerely,

Jennifer Homendy

Chair

cc: Hearing Clerk/OALJ

DEA

DEA Federal Register Representative/DPW

DEA



ALAN WILSON ATTORNEY GENERAL

June 20, 2024

Filed via the Federal eRulemaking Portal

Drug Enforcement Administration Attn: Administrator 8701 Morrissette Drive Springfield, VA 22152

RE: Docket No. DEA-1362, "Schedules of Controlled Substances: Rescheduling of Marijuana"

Dear Administrator Milgram:

We, the undersigned state Attorneys General, write in support of requests for a public hearing on the Proposed Rule, 89 Fed. Reg. 44,597 (May 21, 2024), which would reschedule marijuana from a Schedule I drug to a Schedule III drug under the Controlled Substances Act, 21 U.S.C. § 801, et seq. ("CSA"). Considering the potential impacts of the Proposed Rule, a public hearing is in the public interest, and therefore in the interest of our states.

First, rescheduling marijuana as a Schedule III drug is likely the most consequential rulemaking DEA has ever undertaken. The Proposed Rule carries both national and international ramifications. It would change the definition of currently accepted medical use and would alter the way the federal government implements international treaty obligations under the United Nations' Single Convention on Narcotic Drugs. The Proposed Rule also represents the most significant relaxation of narcotics restrictions in the history of the CSA. Such sweeping changes cannot properly be made in the absence of a robust administrative record. That's why Congress required such decisions to be made on the record with an opportunity for a public hearing.

Second, a hearing would aid DEA's evaluation of the important sociological and scientific issues at stake in any major shift in drug classification. As DEA made clear in the Proposed

¹ See, e.g., NATIONAL DRUG AND ALCOHOL SCREENING ASSOCIATION, Comment on Proposed Rule 89 Fed. Reg. 44,597, DEA-2024-0059-20317 (Jun. 17, 2024).

Rule, additional data and rigorous scientific analysis is needed to determine whether marijuana may be appropriately assigned to Schedule III. A hearing is needed to sort through competing claims about marijuana's pharmacological effects, potential for abuse, and impacts on public safety. Such a hearing would allow outside experts to present their views on the most current evidence on those topics, and their presentations would be subject to cross-examination. It would also allow local leaders, law enforcement groups, and advocacy organizations to speak on the complexity of this issue.

Reclassifying any drug from Schedule I to Schedule III is a significant change. Especially considering how politically fraught the topics of marijuana use and legalization have become, a dramatic change in the classification of marijuana should not be done lightly or without sufficient public input. DEA should hold a public hearing on the Proposed Rule.

Respectfully,

Alan Wilson

Attorney General of South Carolina

Man Wilson

Steve Marshall

Attorney General of Alabama

Tim Griffin

Attorney General of Arkansas

· Labrador

Raúl Labrador

Attorney General of Idaho

Todd Rokita

Attorney General of Indiana

Brenna Bird

Attorney General of Iowa

Kris Kobach

Attorney General of Kansas

Liz Murrill

Attorney General of Louisiana

Lynn Fitch

Attorney General of Mississippi

Austin Knudsen

Attorney General of Montana

Mike Hilgers

Attorney General of Nebraska

Bridget Hill

Attorney General of Wyoming

John M. Formella

Attorney General of New Hampshire

4 M. Fle

Drew Wrigley

Attorney General of North Dakota

Gentner Drummond

Attorney General of Oklahoma

Marty Jackley

Attorney General of South Dakota

Ken Paxton

Attorney General of Texas

Sean Reyes

Attorney General of Utah



United States Cannabis Coalition PO Box 329 Marietta, OK 73448

June 20, 2024

Drug Enforcement Agency 8701 Morrissette Drive Springfield, Virginia 22152

Re: Docket No. DEA-1362 (courtesy copy)

Attn: Attn: Hearing Clerk/OALJ,

I am writing to formally request a meeting and public hearing with the Drug Enforcement Administration to discuss the current re-scheduling of cannabis under the Controlled Substances Act. The scientific evidence and shifting societal attitudes strongly indicate that cannabis's current Schedule I classification is no longer tenable.

However, I want to caution against the possibility of cannabis simply being rescheduled to Schedule III. While this would represent an improvement over the status quo, in many ways it could be just as problematic, if not worse, than the current paradigm.

Schedule III substances are still considered to have an accepted medical use, but also a moderate to low potential for abuse and physical/psychological dependence. This would subject cannabis to a complex web of regulatory requirements and restrictions that could severely limit patient access and the development of a legitimate, regulated industry.

Rescheduling cannabis to Schedule III could also perpetuate many of the same law enforcement and criminal justice issues that we've seen with the current Schedule I status. Police could still use the presence of cannabis as probable cause for searches and arrests. Individuals could face felony charges for possessing or distributing amounts that exceed arbitrary thresholds.



In contrast, the only reasonable path forward is the full de-scheduling of cannabis from the Controlled Substances Act altogether. This is the approach taken by both the Democrat-sponsored Marijuana Opportunity Reinvestment and Expungement Act (H.R.3617) and the Republican-sponsored Common Sense Cannabis Reform for Veterans, Small Businesses, and Medical Professionals Act (H.R.1017)

De-scheduling would allow states to regulate cannabis as the people they represent see fit per the 10th Amendment of the U.S. Constitution; moreover, it would remove the current barriers to research, medical use, and the development of a legitimate, safe industry. It would also eliminate the racially disparate enforcement and criminalization that has defined the failed "War on Drugs."

I believe a thorough, evidence-based review by the DEA would inevitably lead to this conclusion. That is why I am once again formally requesting an in-person meeting, as well as a public hearing where medical experts, patients, and other stakeholders can provide testimony on this critical issue.

The health and well-being of the American people are at stake. I look forward to working constructively with the DEA to chart a new, sensible path forward on cannabis policy. Please let me know how I can assist in this process.

Sincerely,

Patrick H Moore

Director

United States Cannabis Coalition



2°* 10 26 14 00 10

NY Small Farma Ltd

Filed: 02/17/2025

728 Broadway Kingston, NY 12401

Tel. 212-460-8643 www.nysmallfarma.org

Drug Enforcement Administration Attn: Administrator 8701 Morrissette Drive Springfield, Virginia 22152

> Re: Request to be considered to testify at hearing for Docket No. DEA-1362 - Rescheduling of Marijuana

Dear Drug Enforcement Administrator:

My name is Nicole Ricci. I am the president of New York Small Farma Ltd. ("NYSF") is a New York (NY) not for profit and 501(c)(3) educational organization headquartered in Ulster County, NY and focused on regenerative production of adult-use cannabis. We host science-based education programs for the NY community, the consumer, and the industry stakeholders on the importance and benefit of an adult use cannabis production program that has a low carbon footprint, is consciously grown within the ecological limits of this planet and is grounded in opportunity for all. NYSF was founded in 2019 and our mission is to foster a socially just, environmentally regenerative, and economically inclusive cannabis community. NY state is the largest consumer population of adult use cannabis in the world and its prohibition laws were among the most racist in the country.

Background on NYSF

From its inception, NYSF has worked to ensure the future of NY cannabis is environmentally and economically sustainable. We were instrumental in procuring the environmental provisions: to improve climate resiliency and protect the environment into the intent of Marihuana Regulation and Taxation Act (MRTA), now the NY Cannabis Law. NYSF was also instrumental in securing provisions in the MRTA calling for cannabis cultivation practices to be guided by regenerative practices and standards as well as expanding the definition of distressed farmer. We were an instrumental part of a coalition of activist who worked to ensure the law was rooted in social justice and incorporated a provisions specifically to redress communities disproportionately impacted by the racist implementation of prohibition laws and policies.

During the drafting of the regulations that now govern the implementation of NY's Cannabis Law, the organization worked closely with regulators to ensure the law's focus on environment and justice were carried forward in the rules that govern homegrow and licensed cannabis

No. DEA-1362 -Rescheduling of Marijuana

production. For the past three years the organization has been coordinating and delivering education and outreach to community and industry stakeholders on the new regulations and facilitated public comment into the process. Through our work we have cultivated expertise in NY regulations, compliance, and market trends. Our educational events include, we hosting classes, workshops, and webinars to prepare and educate the public on what was written in the MRTA and the regulations and how those provisions affect each stakeholder. Our classes and webinars are consistently attended by hundreds of participants. Concurrently we have worked with regulators to provide science-based approach to cannabis production. We served as a State Technical Partner during licensing and post licensing. We advocate for policies and regulations that further the provisions of the MRTA, such as those that favor and support social and economic equity applicants and licensees; encourage an end to the illicit market by providing fair pathways for traditional market growers and operators; and improve climate resilience. Our stakeholders include cannabis consumers, industry members, traditional market growers, like-minded organizations, and government officials.

Our main focus in assisting small businesses and in particular small, craft cultivators launch and maintain successful, low carbon operations. Part of the focus on the MRTA was to revitalize NY's agricultural sector. The U.S. has seen a decline in food production and agricultural land with an increase in relying on importing food to feed Americans. We host an annual farmers forum which provides science-based education to current cannabis farmers with a focus on the small, family run farm. We hosted the first licensed cannabis farmers forum and regenerative cannabis conference in the state.

We partnered with the Office of Cannabis Management (OCM) to develop clear pathways for traditional market growers (illicit growers) into the regulated market. Through our collaboration, the Cannabis Compliance Training and Mentorship (CCTM) program was developed. NYSF provided the basis for the curriculum for that program and organized meetings between traditional market entrepreneurs who were also social and economic equity and OCM. In addition to working within the industry, NYSF also provides general consumers without any cannabis business background, classes and webinars to assist them in learning about cannabis, home cultivation, and what opportunities exist for entrepreneurs and workforce in the new industry.

Presently, NYSF works with a network of current and future cannabis cultivators and microbusiness owners who represent social and economic equity and legacy operators. We assist our network of licensed farmers in setting up and sustaining regenerative, small-scale, low carbon footprint operations as well as baseline assessments for transitioning farms to fully regenerative. We also assist these operations in developing and implementing environmental sustainability plans as well as community development plans. We also run an industry incubator for Ulster County and were recently awarded a state grant to assist the industry in maintaining complaint production operations.



NY Small Farma Ltd

728 Broadway Kingston, NY 12401

Tel. 212 460 8643 www.nysmallfarma.org

Our science-based approach to plant education involves working with several of NY educational institutions on plant research. Through partnership with Columbia University and Adult Use Conditional Cultivators (AUCC) farmers, NYSF is currently engaged in research on sustainable cannabis production, that will look at the chemical composition of cannabinoids grown under different light conditions and a separate study to look at cannabinoid and terpene conditions at different intervals postharvest. NYSF is also working with SUNY schools to develop a curriculum that will provide SUNY student with access to plants in the field and workforce training videos for cultivation, harvest, and post-harvest education series. Due to on-farm partnerships with several AUCCs, these studies are currently underway for this grow season.

Our future plans involve obtaining a research and development license from the OCM for a NYSF owned and operated incubator focused on community-based economic development. The incubator will serve as a resource to provide land access and business assistance to traditional growers and equity applicants/licensees seeking microbusiness, tier 1 and tier 2 licenses. In addition to cultivation knowledge and land access, NYSF Incubator Program will provide small cannabis farmers and equity licensess with resources, mentors, and one-on-one training to develop their techniques and business skills to run successful regenerative-based micro, craft, and small farm enterprises. The mission of the incubator is to foster a socially just, environmentally regenerative, and economically inclusive cannabis community by supporting equity entrepreneurs, experienced cultivators, and researchers launch regenerative farms/studies rooted in community development.

NYSF envisions a dotted corridor of microbusiness farms throughout the Hudson River Valley region that draws tourists from within NY, the U.S., and internationally to the area to visit these farms and the towns where they are located. Many upstate areas are economically depressed. Under the current regulations, microbusinesses are permitted to be vertically integrated, and host onsite consumption operations. If well planned and structured, these farms stand to not only attract visitors from all over but create a network of ancillary and support businesses providing many depressed areas with a new industry, economic development, and tax revenue opportunities that cannot be found elsewhere.

The economy from these farms and the supportive business in the area has the potential to be quite vast and contribute not only to NY's economy but that of the country as a whole.

Ensuring not only that these farms are established but thrive is an essential role of the NYSF programming. The alternative to multiple small-owned farms are large-corporate scale monocrop cannabis farms. History has shown that an abundance of micro-sized and small-scale farms not only employ more workers over time, but they also create a multiplier effect in the

economy opening up opportunities for ancillary and support businesses for agriculture and tourism. Research has also shown that dollars earned by smaller operators stay in the community. In contrast larger, corporate operations tend to leach profits to out of state back to their headquarters. Multiple smaller operations create a more stable community-based economy. If several farms fail, the community can absorb this loss whereas when big box,

corporate operations close, they displace large numbers of workers all at once, decimating entire towns and communities. Further, indoor operations, which are typically how corporate grows are cultivated, have a significant impact on carbon emissions and the NY energy grids.

NYSF Position on Rescheduling:

We concur with the findings that marijuana is eligible for rescheduling and maintain that it's listing as a Schedule I was inaccurate and not in accord with the requirements of a Schedule I drug. While we are in accord with the finding that there are multiple currently acceptable applications of marijuana medically, and there is credible scientific and medical support and experience prescribing marijuana as medication, we do not agree with the assessment that marijuana poses the level of addiction either psychologically or physiologically that a Schedule III listing is required to meet. Further there is a preponderance of literature documenting that most past research studies conducted on marijuana were specifically organized to prove negative attributes versus objectively assess its healing properties. More modern research conducted post state legalization has provided a more robust and accurate depiction of the medicative properties of the plant. We further note that it is in fact a plant. While one can process the flower and other parts of the plant to create value added products or other types of products and medicine, it is most often consumed in its natural and unaltered state as a plant flower and not a medicine made in a laboratory.

We urge you not to reclassify marijuana as a Schedule III, which will include additional controls that may conflict with safe and successful state programs, including personal cultivation. In addition, placing marijuana in such a category will make it difficult for small businesses to compete with large corporations that make up the U.S. big pharmaceutical companies. In addition, any reclassification would require adjustments to federal policies in order to make marijuana readily available for research studies, in particularly by small organizations such as NYSF. It would be more appropriate to DEschedule marijuana and turn the regulation of the plant over to states until the federal government is poised to adopt federal legalization. Most importantly, the federal government should immediately decriminalize marijuana and adjust tax and banking laws that would enable safer and more prosperous state programs. As it stands small businesses struggle under banking and insurance policies that are weighted against them due to the inappropriate classification of this plant at the federal level.

If the will of the federal body is not yet to fully deschedule this plant, at minimum do not take it from one wrong classification to another. A more appropriate scheduling would be at a Schedule IV or V. Ultimately, we would like to see the sanctity of the Classification of Substance Act remain intact by ensuring all classifications are science based and reasonable and not guided by political fears. Wherever the federal government lands on classification and



NY Small Farma Ltd

Filed: 02/17/2025

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criminalization of this plant, it should not interfere with State programs in anyway and it should not create a scenario that made conditions favorable to corporations and burdensome to small businesses. Such a scenario would be to the detriment of the citizens of this nation and only give rise and renewed energy to an illicit market.

We would welcome the opportunity to present our findings and positions at a hearing and thank you for your work and needed attention to this issue.

Respectfully,

Nicole

Nicole Ricci, President

CC: DEA, Federal Register Representative

CENTER FOR MEDICINAL CANNABIS RESEARCH

Director: Igor Grant, MD

Co-Directors: J Hampton Atkinson, MD; Thomas D Marcotte, PhD

UC San Diego

220 Dickinson Street, Suite B | San Diego, CA 92103 | www.cmcr.ucsd.edu | 619.543.5024



July 19, 2024

Drug Enforcement Administration Attn: Administrator 8701 Morrissette Drive Springfield, VA 22152

Re: Docket No. DEA-1362

To Whom It May Concern:

By way of background, the Center for Medicinal Cannabis Research (CMCR) has been at the forefront of advancing science and policy relating to the potential clinical benefits and limitations of cannabis and cannabinoids as medicine for 24 years. Funded by the California State Legislature in the year 2000, the CMCR initiated the first therapeutic studies using smoked cannabis in over 20 years, and completed key studies regarding the short-term benefits of cannabis for the treatment of neuropathic pain and spasticity. Over the ensuing years the CMCR has conducted numerous Federally compliant (DEA, FDA) clinical trials, funded by the National Institutes of Health, the State of California, and philanthropy. In addition to medicinal studies, the CMCR has completed high profile studies regarding the public safety impacts of cannabis use on driving, including close, novel collaborations with law enforcement.

As Director of the CMCR, I request the opportunity to express at a hearing my concerns regarding the limitations of the proposed rescheduling with respect to facilitating and advancing research on the possible positive, and negative, effects of cannabis on medical and psychiatric symptoms, as well as public safety. This includes the ability to perform medical research on the types of cannabis products that people are actually using. This limitation in our view continues to pose a significant public health challenge to people in the United States because they are denied access accurate information on benefits and risks of these products.

Sincerely,

Igor Grant, M.D.

Mary Gilman Marston Distinguished Professor

Director Center for Medicinal Cannabis Research (CMCR)

UC San Diego, Department of Psychiatry

CC:

DEA, Attn: Hearing Clerk/OALJ, 8701 Morrissette Dr, Springfield, VA 22152

DEA, Attn: DEA Federal Register Rep/DPW, 8701 Morrissette Dr, Springfield, VA 22152

USCA Case #24-1365 Document #2100970 Filed: 02/17/2025 Page 135 of 214



[EXTERNAL] Written Notice of Participation in the December 2nd Public Hearing on Descheduling Cannabis

From Platinum Toast <shanildo44@gmail.com>
Date Mon 8/26/2024 5:25 PM
To NPRM <NPRM@dea.gov>

Shane Gallichio

Lafayette, NJ 07848

08/26/2024

Drug Enforcement Administration Attn: Public Affairs Office 600-700 Army Navy Drive Arlington, VA 20537

Dear Sir/Madam,

Written Notice of Participation in the December 2nd Public Hearing on Descheduling Cannabis

I am writing to formally notify the Drug Enforcement Administration (DEA) of my intention to participate in the upcoming public hearing scheduled for December 2nd, 2024, regarding the descheduling of cannabis.

As an advocate for drug policy reform, Medical Marijuana patient, and a proponent of evidence-based approaches to drug regulation, I am eager to be present for the discussion on this important issue. The potential descheduling of cannabis presents a critical opportunity to reassess and potentially reform our national drug policies, and I look forward to engaging in a constructive dialogue with other stakeholders.

Please provide any additional information or instructions needed for my participation. If there are specific guidelines or procedures that I need to follow, kindly let me know at your earliest convenience.

Thank you for considering my participation in this significant public hearing. I look forward to contributing to the conversation and working towards informed policy changes.

Sincerely,

Shane Gallichio

USCA Case #24-1365 Document #2100970 Filed: 02/17/2025 Page 136 of 214



[EXTERNAL] Re: "Docket No. DEA-1362"

From Brian Austin <bri> stianraustin@icloud.com>
 Date Thu 8/29/2024 5:32 PM

To NPRM < NPRM@dea.gov>

My mailing address is 1955 Upton Talley Road Upton KY 42784. My phone number again is 270-268-8671. This is the logistic confirmation to send me anything from my first email regarding the same topic.

Brian Austin Warrior quest

On Aug 29, 2024, at 5:41 PM, Brian Austin <bri>hrianraustin@icloud.com> wrote:

"Docket No. DEA-1362"

I am requesting to be a participant in the upcoming DEA docket 1362 any information or process that I need to follow other than this written email request. Please let me know. I can also be reached by phone at 270268-8671.

I look forward to the opportunity to provide my testimony in person thank you very much. Have a nice

Brian Austin Warrior quest From: Ms. Cris <crisericson7@gmail.com> Sent: Thursday, August 29, 2024 11:51 PM

al taylor; admin@legalmarijuananowmn.org; shereekrider@usmjparty.com; NPRM To: Subject: [EXTERNAL] To: nprm@dea.gov I would like to participate in the Hearing on

Rescheduling Cannabis

Attachments: Screenshot 2024-08-30 12.22.20 AM.png; Screenshot 2024-08-28 8.29.25 PM.png;

MyCard (1).png; CRISd.jpeg; Crisc.jpeg; Crisb.jpeg; CrisCSpan.webp; dna.jpg

I would like to participate in the Hearing on the rescheduling of marijuana marihuana cannabis. I have been interested in the subject starting with a visit to the Hemp Lawn Farm on the Benson Pike in Shelbyville, Kentucky where my grandfather was born. Scroll down below my art and music to documents and letters from the farm at https://crisericson2022.wordpress.com I have been a perennial political candidate advocating marijuana legalization starting 2002 in Vermont.

This year, I am a write-in candidate, at age 72,

because I now have bi-lateral arthritis and do not walk well enough

to go out and collect ballot access petition signatures.

My current primary care doctor knows I have arthritis from the x-rays and visual inspection of my body, but refuses to prescribe any pain relief medication.

I do not use or grow marijuana cannabis. I am patiently waiting for it to become entirely legal so I don't have to be insulted by any doctor anymore.

I told the current primary care doctor that I did my research on Google, and he said,

"google! Dr. Google! I've been to medical school for 12 years!" He failed to recognize that I am a senior citizen adult and I have every right to be interested in researching my body and medical issues for a person my age on the internet. For him to be upset that I have the intelligence to research medical issues just shows that he is suffering from low self esteem because he feels so angry at me and "Dr. Google". After he said that he had been to medical school for 12 years, I said, "I know, I researched you, too."

Then he glared at me in fury and started telling me about the cold winter winds where he used to live about a year ago and that the cold winds sliced the body like a "machete".

This behaviour of this doctor is not the only intimidating behaviour of doctors I have been exposed to.

If my experience is common, or if even a fraction of people over age 70 have felt threatened by their medical

doctors just because they do their own research and have concluded that half the senior citizen prescription drugs are doing us more harm than good, if my experience is at all similar to other senior citizens, then this must be known and shared.

Vote for Write-in Candidate Cris Ericson on Nov. 5, 2024

Write-in Candidate for US Senate Vermont

http://vt2024.com ru18vote@gmail.com

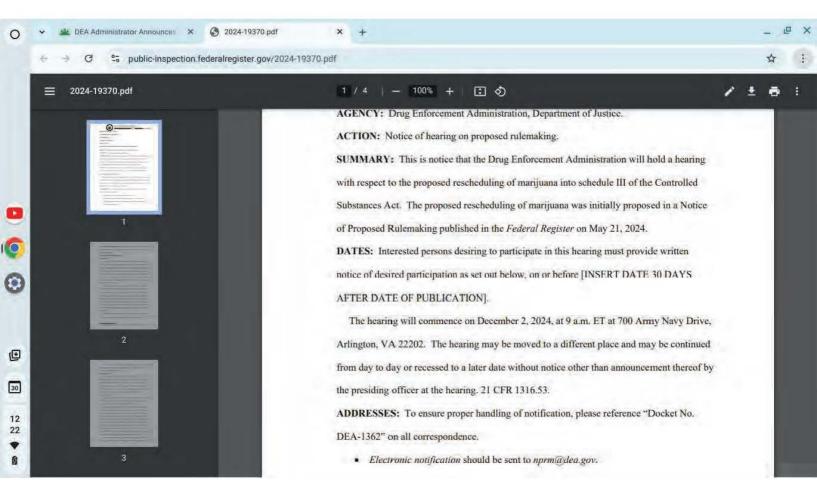
VERMONT

Endorsed by the Legal Marijuana Now Party of MN LegalMarijuanaNowParty.com



Filed: 02/17/2025

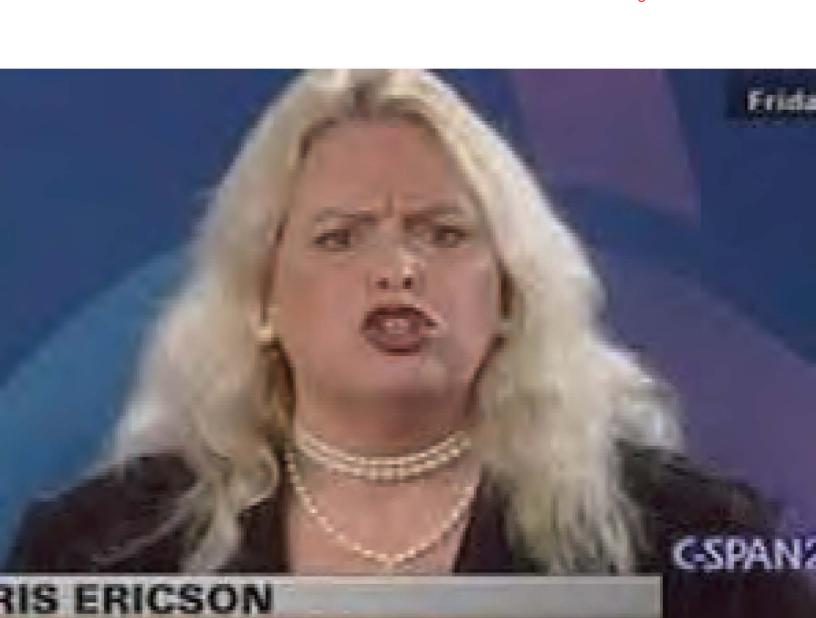
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USCA Case #24-1365 Document #2100970 Filed: 02/17/2025 Page 141 of 214



USCA Case #24-1365 Document #2100970

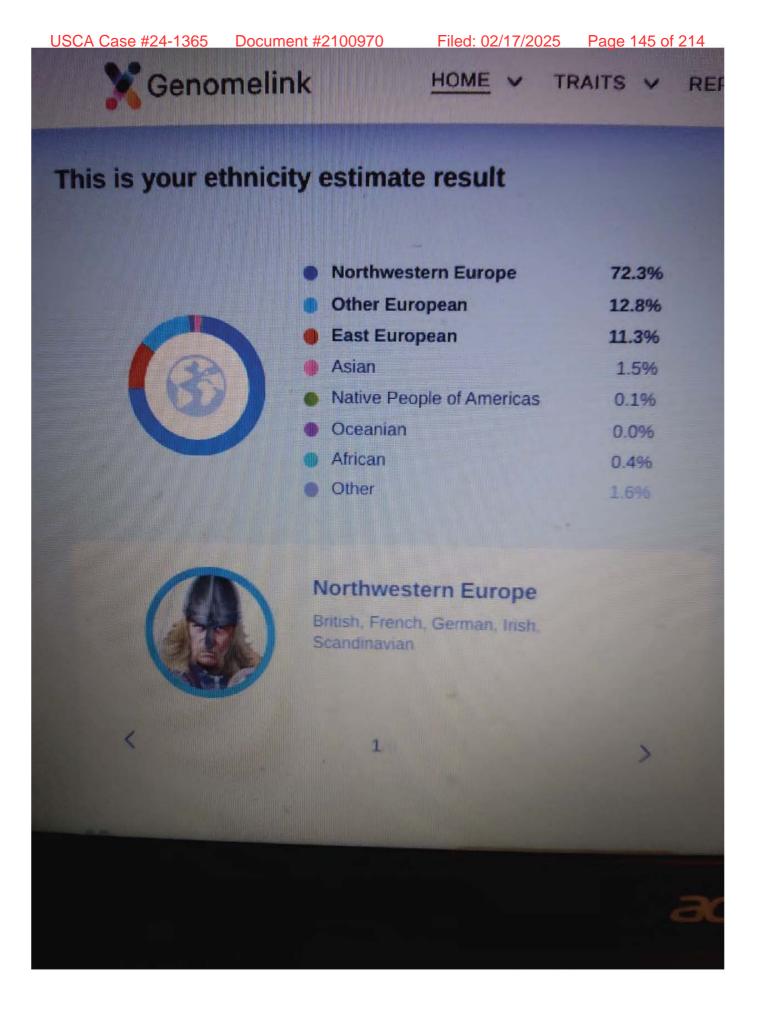


I.S. Senate Candidate Iariiuana Party - Vermont 

USCA Case #24-1365

Filed: 02/17/2025





NOTICE OF APPEARANCE INTENTION TO PARTICIPATE

August 29, 2024

Drug Enforcement Administration Attn: Administrator 8701 Morrissette Drive, Springfield, Virginia 22152.

VIA Email: nprm@dea.gov

Subject: Notice of Appearance | Intention to Participate | Docket No. DEA-1362

Dear Sir:

Please take notice that Ronald Lipof respectfully requests to appear in the matter of: Docket No. DEA-1362, a hearing to consider differing opinions as it relates to the Justice Department's proposal to federally reschedule marijuana.

(A) (State with particularity the interest of the person in the proceeding.).

I am particularly interested in appearing at the proceeding to consider differing opinions on the Justice Department's proposal to federally reschedule marijuana due to my extensive experience in the legal cannabis industry and my role as a strategic advisor to businesses navigating this complex regulatory environment. As the President & CEO of Prince Lobel Strategic Advisors LLC, I have guided numerous cannabis-related enterprises through critical growth phases, including compliance, licensing, and mergers and acquisitions. My expertise has allowed me to witness firsthand the economic and social implications of current cannabis regulations.

Rescheduling marijuana has the potential to significantly impact the industry by altering the legal and financial landscape, affecting everything from federal taxation under IRS code 280E to access to capital and market expansion opportunities. I believe my insights can contribute meaningfully to the discussion, ensuring that the final decision is informed by practical considerations that will foster economic growth, job creation, and social equity within the cannabis industry. My participation will provide a well-rounded perspective that integrates both economic and practical considerations, crucial for understanding the broader implications of rescheduling cannabis at the federal level.

(B) (State with particularity the objections or issues, if any, concerning which the person desires to be heard.).

While most comments and testimony provided to the committee will likely focus on the scientific review into marijuana that led to the reclassification recommendation, I request to be heard on the significant positive economic impacts of rescheduling cannabis. Specifically, I wish to address:

The Economic Case for Rescheduling Cannabis: Rescheduling cannabis could unlock new economic opportunities, including the potential for job creation, market expansion, and increased investment. The cannabis industry is already a significant contributor to the U.S. economy, and rescheduling could further accelerate growth by removing existing barriers.

The Tax Case for Rescheduling Cannabis: By reclassifying cannabis, businesses in the industry would no longer be subject to the strict limitations of IRS code 280E, allowing them to take standard tax deductions for ordinary business expenses. This change would increase the profitability of cannabis businesses, leading to higher tax revenues at the local, state, and federal levels.

The Access to Capital Case for Rescheduling Cannabis: Rescheduling would likely increase access to capital from both banks and private investors by reducing the perceived risk associated with investing in cannabis businesses. This influx of capital would enable further growth, innovation, and job creation within the industry.

These considerations are crucial for understanding the broader economic and financial implications of rescheduling cannabis, and I believe they deserve thorough examination in the upcoming proceedings.

(C) (State briefly the position of the person with regard to the particular objections or issues.).

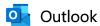
I am of the position that deciding not to reschedule cannabis at this time would hinder significant economic opportunities, maintain an unfair tax burden on legal cannabis businesses due to IRS code 280E, and continue to limit access to capital for an industry that could otherwise thrive under a more favorable regulatory environment. The refusal to reschedule would perpetuate the existing challenges faced by the legal cannabis market, slowing growth, innovation, and the potential for job creation and tax revenue generation.

All notices to be sent pursuant to this appearance should be addressed to:

Ronald Lipof 10401 N 100th Street, #5 Scottsdale, AZ (617) 716-6117 rlipof@princelobelstrategicadvisors.com

Respectfully yours,

Rundllgig



[EXTERNAL] Docket No. DEA-1362"

From Roneet Lev <roneetlev@gmail.com>Date Fri 8/30/2024 9:08 AMTo NPRM <NPRM@dea.gov>

I would like to testify in this hearing on rescheduling marijuana.

I am an emergency and addiction physician and Vice President of IASIC, the a international Academy on the Science and Impact of Cannabis.

Roneet

Roneet Lev, Md

HighTruths.com IASIC1.org

Filed: 02/17/2025

National Transportation Safety Board

Office of the Chair Washington, DC 20594

August 30, 2024

US Drug Enforcement Administration Attn: Hearing Clerk/OALJ 8701 Morrissette Drive Springfield, VA 22152

Subject: Notice of Appearance

Dear Sir:

Please take notice that Jennifer Homendy, Chair, National Transportation Safety Board (NTSB), will appear in the matter of: Schedules of Controlled Substances: Rescheduling of Marijuana (Docket Number DEA-1362).

(A) Interest

The NTSB is an independent federal agency charged by Congress with investigating every civil aviation accident in the United States and significant events in the other modes of transportation–railroad, transit, highway, marine, pipeline, and commercial space. We determine the probable causes of the accidents and events we investigate and issue safety recommendations aimed at preventing future occurrences. The NTSB is a public health authority for purposes of federal health information privacy laws; we conduct public health activities intended to prevent or control injury.¹

Through our accident and incident investigations and transportation safety research, the NTSB has developed experience with marijuana use among noncommercial and commercial vehicle operators and other transportation safety-sensitive personnel. We recognize that marijuana is a prevalent drug with performance-impairing effects, that human performance is critical to the safe operation of transportation systems, and that most people interact with transportation systems multiple times per day. Consequently, we believe that interactions with transportation systems are among the most important ways in which the public may be exposed to risk from marijuana's effects. This perspective has informed our related recommendations to improve transportation safety.

See 79 Federal Register (FR) 28970 and Title 49 Code of Federal Regulations (CFR) 831.9(b)(2).

2

As chair of the NTSB, I affirm my interest in this hearing, and I respectfully request the opportunity to present our concerns about the potential transportation safety consequences of the proposed rule to transfer marijuana to Schedule III of the Controlled Substances Act.

(B) Issues

Well-established scientific evidence shows that marijuana impairs the abilities needed to safely operate a vehicle and to perform other safety-related tasks. Marijuana can adversely affect performance by slowing reaction time, altering perception, and impairing sustained attention, planning, decision-making, and risk assessment.² In our investigations, the NTSB has repeatedly identified toxicological findings indicative of marijuana use by noncommercial and commercial vehicle operators.³ Our 2022 safety research report, *Alcohol, Other Drug, and Multiple Drug Use*

² Compton, R. 2017. <u>Marijuana-Impaired Driving: A Report to Congress</u>. DOT HS 812 440. Washington, DC: National Highway Traffic Safety Administration.

³ Some of the NTSB-investigated events that have occurred since 2022, for which dockets have been published, and for which at least one vehicle operator toxicology test was positive for the primary psychoactive substance in marijuana or one of its metabolites, include the following:

Aviation Investigation Final Report, <u>Bay Minette</u>, <u>Alabama</u>, <u>March 11</u>, 2022 (<u>ERA22FA153</u>)

[•] Intersection Crash Between Passenger Car and Combination Vehicle, Tishomingo, Oklahoma, March 22, 2022, <u>HIR-24-04</u> (<u>HWY22FH008</u>)

[•] Aviation Investigation Final Report, Sausalito, California, May 6, 2022 (WPR22FA172)

Aviation Investigation Final Report, Valdez, Alaska, July 11, 2022 (ANC22FA053)

[•] Collision between Amtrak Passenger Train and Union Pacific Railroad Roadway Maintenance Machine, Oakland, California, July 15, 2022, RIR-23-11 (RRD22FR011)

[•] Aviation Investigation Final Report, Seguin, Texas, July 22, 2022 (WPR22FA264)

Collision between US Coast Guard Cutter Winslow Griesser and Center-console Boat Desakata, Atlantic Ocean, Near Dorado, Puerto Rico, August 8, 2022, MIR-23-14 (DCA22PM034)

[•] Aviation Investigation Final Report, Hanna City, Illinois, August 13, 2022 (CEN22FA383)

Aviation Investigation Final Report, <u>Watsonville</u>, <u>California</u>, <u>August 18</u>, <u>2022</u> (<u>WPR22FA309</u>)

Aviation Investigation Final Report, Scio, Oregon, August 21, 2022 (WPR22FA312)

[•] Ongoing highway investigation, Goodyear, Arizona, February 25, 2023, see the "Medical Factual Report" (HWY23FH008)

Ongoing highway investigation, Woodlawn, Maryland, March 22, 2023, see the "Medical Factual Report" (HWY23FH010)

The <u>public dockets</u>, and in some cases final reports, for these events can be viewed using the <u>CAROL Query</u>. This list is not intended to be comprehensive, nor were marijuana's effects necessarily causal or contributory in the listed events. Cases in which the NTSB has cited marijuana's effects in the probable cause can be found by using the <u>CAROL Query Custom Search</u> and searching the "probable cause" field for "marijuana," "cannabis," or "tetrahydrocannabinol."

Document #2100970

Among Drivers, found that marijuana was the second-most commonly detected potentially impairing drug among study drivers, after alcohol.4

In commercial transportation operations, the NTSB is concerned that the proposed rule would prevent continued testing for marijuana use by safety-sensitive employees who are subject either to the US Department of Transportation (DOT) drug testing under Title 49 Code of Federal Regulations (CFR) Part 40, or (as is the case for many air traffic controllers) to federal workplace drug testing under US Department of Health and Human Services (HHS) Mandatory Guidelines for Federal Workplace Drug Testing Programs using Urine and Oral Fluid (HHS Mandatory Guidelines). The Omnibus Transportation Employee Testing Act of 1991 requires the DOT to conform its drug testing procedures with HHS guidelines for federal workplace drug testing, including using HHS-certified laboratories.⁵ Executive Order 12564, which required federal executive agencies to develop drug-free workplace programs, including employee testing for illegal drug use, defines "illegal drugs" to include only Schedule I and II controlled substances. 6 The HHS Mandatory Guidelines authorize testing for Schedule I and II controlled substances only. 7 Therefore, the NTSB is concerned that marijuana testing under 49 CFR Part 40 and HHS Mandatory Guidelines would be prevented as an indirect effect of the proposed rule because the HHS-certified laboratories used for such testing are not authorized to test for Schedule III controlled substances.8

We also have broader concerns related to the transportation safety effects of marijuana rescheduling that are not limited to drug testing in commercial operations. Marijuana rescheduling has a potential to affect everyone who interacts with transportation systems and infrastructure, from vehicle operators and passengers to pedestrians and bystanders. Anticipating and

⁴ See NTSB. 2022. Alcohol, Other Drug, and Multiple Drug Use Among Drivers. SRR-22-02. The safety research included data from four laboratories, each of which provided data from specific populations of drivers (such as drivers arrested for impaired driving, crash-involved drivers arrested for impaired driving, crash-involved fatally injured drivers, and drivers suspected of impaired driving in a crash that involved a fatal or serious physical injury). The safety research did not distinguish between commercial and noncommercial drivers.

Omnibus Transportation Employee Testing Act of 1991, Public Law 102-143, 105 Stat. 952 (1991).

⁶ See <u>51 FR 32889</u>.

⁷ See 88 FR 70768 and 88 FR 70814.

⁸ During testimony before the House Committee on Transportation and Infrastructure on June 27, 2024, the US Secretary of Transportation indicated the DOT did not believe the proposed rescheduling action would directly affect marijuana testing of safety-sensitive transportation employees who are subject to DOT regulation or employed by the DOT. The secretary stated that the DOT was continuing to evaluate indirect effects of the proposed rescheduling action. See the hearing titled Oversight of the Department of Transportation's Policies and Programs and Fiscal Year 2025 Budget Request (statement of Pete Buttigleg, Secretary, DOT).

4

mitigating the transportation safety risks of rescheduling marijuana will require diligent consideration of scientific evidence and expert insight.

(C) Position

The NTSB has made no recommendation concerning marijuana's scheduling under the Controlled Substances Act. However, in our July 19, 2024, comments on the US Drug Enforcement Administration's (DEA) notice of proposed rulemaking titled "Schedules of Controlled Substances: Rescheduling of Marijuana," we urged the DEA to do the following:

- Ensure that any final rule to reschedule marijuana does not compromise marijuana testing under DOT and HHS procedures applicable to safety-sensitive transportation employees.
- Scrutinize how a DEA determination about marijuana having a currently accepted medical use in treatment in the United States might affect a safety-sensitive transportation employee's ability to present medical marijuana use as a legitimate medical explanation for a positive marijuana result on a DOT or federal workplace drug test.
- Diligently examine the multifaceted transportation safety implications of marijuana rescheduling.
- Proactively educate the public that marijuana rescheduling does not imply that driving or performing other safety-sensitive transportation tasks under the influence of marijuana is safe or legal.
- Seek specific expertise to avoid unintended consequences of changes affecting 21 CFR Part 1308 definitions, including the definitions of tetrahydrocannabinols, marijuana extract, and (as newly proposed) naturally derived delta-9-tetrahydrocannabinols.

The NTSB appreciates the opportunity to participate in the upcoming hearing.

⁹ NTSB. <u>July 19, 2024, comments</u> in response to the DEA's notice of proposed rulemaking published at <u>89 FR 44597</u> on May 21, 2024.

5

All notices to be sent pursuant to this appearance should be addressed to:

The Honorable Jennifer Homendy Chair National Transportation Safety Board 490 L'Enfant Plaza, SW Washington, DC 20594

Respectfully yours,

Jennifer Homendy

Chair

USCA Case #24-1365 Document #2100970 Filed: 02/17/2025 Page 154 of 214

September 3, 2024

Drug Enforcement Administration Attn: Administrator 8701 Morrissette Drive Springfield, VA 22152

Subject: Notice of Appearance

Dear Sir / Madam:

Please take notice that the International Association of Chiefs of Police (IACP) will appear in the matter of: **Docket No. DEA-1362**

The IACP is strongly opposed to the Justice Department proposal to reclassify marijuana from a Schedule I substance to a Schedule III substance under the federal Controlled Substances Act (CSA). This proposed change represents a significant shift in federal drug policy with significant implications for public safety, public health and the ability of police agencies to protect the public.

In particular, the IACP is concerned with the impact that the proposed change could have in the following areas:

- Public Safety Risks
- Youth and Health Impacts
- Workplace Safety
- Impaired Driving
- Legal Standards for Impairment
- Challenges in Implementation
- Policing Challenges
- Potential Impact on Current Firearms Regulations
- Diversion Potential

All notices to be sent pursuant to this appearance should be addressed to:

Gene Voegtlin
Director, Policy and Governance
International Association of Chiefs of Police
44 Canal Center, Suite 200
Alexandria, VA 22314
voegtlin@theiacp.org

Please let us know if you have any questions or require additional information.

Thank you for your attention to this matter.

Sincerely,

Vincent Talucci

Executive Director/Chief Executive Officer

USCA Case #24-1365 Document #2100970 Filed: 02/17/2025 Page 157 of 214



[EXTERNAL] Hearing - marijuana re-Scheduling

From Sandra <szrapke@gmail.com>
Date Wed 9/4/2024 9:14 AM
To NPRM <NPRM@dea.gov>

To whomever it may concern:

I am Sandra Zundell Rapke and I live in CA.

I have used cannabis for recreation for decades. I first tried it at 18 years old in 1969.

I am 72 years old now and use cannabis regularly, in all its forms (gummies, flower, vape) for chronic pain due to inflammatory osteoarthritis and sleep.

As of my last full physical in 2024, my heart health is good. As many my age, I'm in a low dose BP med and a low dose statin. My other tests are also good.

I do not consider myself addicted, per se. it's something that takes the edge off pain between med doses and helps me stay asleep.

Making cannabis a schedule III drug will allow much needed medical research and allow US to become competitive in the market of research into a drug with such potential to improve lives. I have advocated for research for a long time and have supported the UCLA Cannabis Research Project. I would be honored to speak before the hearing panel at any time.

Thank you.

Sandra Z Rapke 310-617-0332

Please do not forward

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September 6, 2024

Drug Enforcement Administration, Attn: Hearing Clerk/OALJ 8701 Morrissette Drive, Springfield, VA 22152



Filed: 02/17/2025

Subject: Notice of Appearance

Dear Sir/Ma'am:

As an interested party, I, Sue Thau, am submitting my request to speak at the hearing regarding the rescheduling of marijuana (Docket No. DEA-1362) and am letting you know of my intention to participate in such hearing. As the Public Policy Consultant representing CADCA, I have been selected by such organizations to speak on their behalf on the particular interests, objections and issues we have concerning Docket No. DEA-1362.

CADCA is the premier substance use prevention association, both nationally and internationally. CADCA is a non-profit which represents over 7,000 community substance use prevention coalitions that involve multiple sectors of a community including schools, law enforcement, youth, parents, healthcare, media, tribal communities and others who are involved in comprehensively addressing locally identified substance use issues. CADCA has members in every U.S. state and territory and in 30 countries around the world. The CADCA coalition model emphasizes the power of community coalitions to prevent substance misuse through collaborative community efforts. CADCA believes that the prevention of substance use and misuse before it starts is the most effective and cost-efficient way to reduce substance use and its associated costs. CADCA opposes the recommendation to move marijuana (also called "botanical marijuana") from Schedule I to Schedule III of the Controlled Substances Act (CSA).

Our particularity of interest in the hearing is that rescheduling marijuana would greatly exacerbate the public health harms it causes, especially as they relate to youth. These harms include cognitive decline (i.e., depression, issues with memory, attention, impaired learning performance, reduced IQ, and early onset of psychiatric disorders, such as schizophrenia)^{1,2} fatal car crashes,³ and risk for developing Cannabis Use Disorder.⁴ Since the beginning of the "medical marijuana" and legalization movement, marijuana products available today are far more potent and have much higher THC content that the "Woodstock weed" of the 1970s. Making these products more potent, more dangerous, and more readily available has resulted in an increase in the percentage of people who use marijuana meeting the DSM-V criteria for substance use disorder.⁵ No research supports the use of wax, shatter, dabs, edibles, drinks or oils for any medicinal purposes. Since the beginning of the "medical" marijuana and legalization movement, perception of harm related to marijuana has plummeted among youth.⁶ Rescheduling marijuana to Schedule III at the federal level will further exacerbate the belief that botanical marijuana is medicine and further reduce the perception of harm and risk associated with it among youth and adults.⁷ Data from the 2023 Monitoring the Future (MTF) Study shows that adult past

500 Montgomery Street, Suite 400 | Alexandria, VA 22314 1-800-54-CADCA | 703-706-0565

¹ Blum, K., Khalsa, J., Cadet, J.L., Baron, D., Bowirrat, A., Boyett, B., Lott, L., Brewer, R., Gondre-Lewis, M., Bunt, G., Kazmi, S., Gold, M.S. (2021 March 30). Cannabis-induced hypodopaminergic anhedonia and cognitive decline in humans: embracing putative induction of dopamine homeostasis. *Frontiers in Psychiatry, Vol. 12.* doi: 10.3389/fpsyt.623403

² Office of the Surgeon General. (2019). U.S. Surgeon General's advisory: Marijuana use and the developing brain. *U.S. Department of Health and Human Services*. https://www.hhs.gov/surgeongeneral/reports-and-publications/addiction-and-substance-misuse/advisory-on-marijuana-use-and-developing-brain/index.html

³ Asbridge, M., Hayden, JA, Cartwright, JL. Acute cannabis consumption and motor vehicle collision risk: systematic review of observational studies and meta-analysis. British Medical Journal, 2012; 344 (ePub): e536. PMID: 22323502.

⁴ Arterberry, B.J. et al. (2018 December 17). Higher average potency across the United States is associated with progression to first cannabis use disorder symptom. Drug and Alcohol Dependence. https://doi.org/10.1016/j.drugalcdep.2018.11.012

⁵ Hasin DS, et al. Prevalence and Correlates of DSM-5 Cannabis Use Disorder. The American Journal of Psychiatry. Dec 2015 http://ajp.psychiatryonline.org/doi/abs/10.1176/appi.ajp.2015.15070907

⁶ University of Michigan, 2023 Monitoring the Future Study.

⁷ Ibid.

USCA Case #24-1365 Document #2100970 Filed: 02/17/2025 Page 159 of 214

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year and past month marijuana use remains historically high. Marijuana edible-related poison control calls among children aged 0-12 increased 3,311% from 2016 to 2022. Current research since the introduction of higher potency marijuana products finds that about 30% of those who use become addicted to it as opposed to approximately 14% previously and are at an increased risk for developing a psychotic disorder. Control of the provious statement of the control of the c

Botanical marijuana does not meet the previous criteria for currently accepted medical use (CAMU), nor does it meet HHS' new definition requiring "widespread current experience with medical use" and "some" credible scientific support for at least one medical use. ¹¹ HHS is conflating isolated cannabinoids in FDA-approved medications with crude marijuana products. It does not follow that the marijuana products available commercially in many states (e.g., wax, shatter, dabs, edibles, oils, etc.), which have no proper dosage and may contain toxic contaminants, will have the same effect as medications with small, specified doses of a single active chemical. ¹² Unlike other drugs in Schedule III, botanical marijuana is not FDA approved to treat or cure any disease and it is not available for prescription in any state.

Based on the issues raised above, CADCA strongly objects to the effort to reschedule marijuana from Schedule I to Schedule III and hopes to be formally selected to participate in the hearing on this issue

All notices pursuant to this appearance should be addressed to:

CADCA C/o Sue Thau/Barrye L. Price 500 Montgomery Street Suite 400 Alexandria, VA 22314

Respectfully yours,

Sue Thau

Public Policy Consultant, CADCA

⁸ NIDA. 2024, August 29. Cannabis and hallucinogen use among adults remained at historic highs in 2023. Retrieved from https://nida.nih.gov/news-events/news-releases/2024/08/cannabis-and-hallucinogen-use-among-adults-remained-at-historic-highs-in-2023 on 2024, September 4

⁹ America's Poison Centers. https://poisoncenters.org/

¹⁰ Di Forti, M., Quattrone, D., Freeman, T.P, Tripoli, G., Gayer-Anderson, C., Quigley, H. (2019 May). The contribution of cannabis use to variation in the incidence of psychotic disorder across Europe (EU-GEI): a multicentre case-control study. *The Lancet Psychiatry, Vol. 6*(5). pp. 427-436

 $^{^{11}}$ International Academy on the Science and Impact of Cannabis. (June 1 2024).

¹² Ibid.

09/07/2024 Docket No. DEA-1362

- I, Mariah Ashley Magnuson, wish to take part in the hearing scheduled on December 2nd, 2024, at 9:00AM ET, (6:00AM PST) at 700 Army Navy Dr. Arlington, VA 22202 for the proposed rescheduling of marijuana into schedule III of the Controlled Substances Act.
- I, Mariah Ashley Magnuson, am a person who would be aggrieved by this rule issuable.
- I, Mariah Ashley Magnuson, object to rescheduling marijuana or any cannabis products into schedule III of the Controlled Substances Act.

There are incredibly positive benefits associated with the use of cannabis products in not only my life but also the lives of countless other citizens of the United States of America and all over the world. CBD for instance, a product of cannabis, helps my body with reducing inflammation, pain, insomnia, and even PMS or premenstrual dysphoric disorder, along with stress and anxiety. Doctors prescribe THC to cancer patients to help them eat. THC and cannabis products have helped my mother immensely with her awful menopause symptoms.

I administer the correct dosage of CBD to my mother's beloved adopted cat, Athena, who was rescued from the pound with her brother Troy, for her severe case of cat herpes which was constantly flaring up on her eyes until I administered the recommended dosage according to her weight. After use of the CBD on Athena, it made our beloved feline show 100% symptom remission. She no longer has those flare ups on both of her eyes and is showing signs of feeling much much better physically and psychologically, they have completely cleared up which I have never seen before in the entirety of her life after adoption from the animal shelter.

The benefits of marijuana continue in not only the lives of humans and animals but also for the environment; the hemp plant can absorb carbon dioxide from the atmosphere more than twice as effectively as trees. Industrial hemp has been scientifically proven to absorb more CO2 per hectare and is therefore the ideal carbon sink. In addition, the CO2 is permanently bonded within the fiber that is used for anything from textiles to paper, and as a building material. Well-planned cannabis cultivation sites can minimize habitat loss and habitat fragmentation, avoid sensitive habitats, and protect fish and wildlife. It helps the economy by increasing tax revenues, job growth, and investment opportunities.

People can abuse anything, and there can always be a negative associated no matter what it is, processed foods for example. The unnatural genetically modified chemicals and additives in our food that is banned in Europe is terrible for our health and wellness as well as the environment if you think about it. Along with the use of pesticides and chemicals. That goes for the way we package everything in the world with plastics and carbon emissions from transportation and processing plants.

We as humans need to rethink the way we are going about life in the world today. An all-natural plant such as marijuana should not be criminalized. We need to rethink the way that we are producing, packaging, distributing, and using products. CBD that comes in a tincture or in the form of a gummy does not produce air pollution because you are not smoking it. We need to choose more sustainable alternatives for packaging all the products we use in life on the day to day. We need to ban plastic and carbon emissions from the planet as well as deforestation and pollution of trash like the use of plastics that end up in the ocean.

As far as criminalization of cannabis goes, an all-natural plant, just like an herb, is nothing compared to the nation's fentanyl crisis wiping out my generation and the ones to come along with the other illicit drugs like heroin and meth which are the real threats to the health and safety of everyone in society.

And for those who think the use of cannabis is causing people to have impaired decision making and slower reaction time, it can be true if using the indica strain which has more sedative properties and is great for nighttime like for me after a long day of work and want to relax and for insomniacs and increases appetites for our poor cancer patients who cannot eat... The sativa strains or sativa dominant hybrid strains are better for daytime use- they help me focus on what I am working on and have lots of fun studying new things I like in my free time doing yoga and meditating surrounded by nature; helps inspire creativity and enjoy what little time we have on this Earth. Negativity blocks creativity and stress and anxiety are negative things. I would hope the DEA would decide that cannabis is not the issue here today. I would hope you can see that when used responsibly as I do, and not abused, cannabis is a good thing in this world. You would not drink and drive or use heavy machinery under the influence of alcohol... Treat the indica strains the same as you would alcohol. Stress and anxiety have a

negative impact on memory, there is a lot of stress and anxiety in the world today- too much going on in the world in every direction and on our screens. Social media and the use of technology like phones and computers for example was detrimental to my mental health (as well as physical i.e., tech-neck, etc). I took a two month break from social media and my stress and anxiety decreased immensely.

If you look at why someone would abuse cannabis, or anything for that matter, substances or even food... there is a much deeper issue than the substance or food itself. There is usually a reason a person would abuse things like that to fill a void within themselves or to self-medicate/cope with life. Look at children who have been abused physically, verbally, or sexually... most of the time they do end up developing some type of unhealthy coping mechanism such as abusing substances or eating disorders or even self harming and other behavioral issues later in life.

We as human beings are on this planet we call home together, there is no other planet Earth in our solar system. Please, let us come together and make healthier life choices for ourselves and for our irreplaceable beautiful blue planet. It takes self awareness, and

Filed: 02/17/2025

healing in body, mind, and spirit to become the best versions of ourselves. Healing ourselves and our land is possible. We need to come together as humanity to help support one another as well as our beautiful blue planet and its amazing diverse ecosystems in our forests and oceans to make a more positive healthier world for you and I and generations to come. We have the power to change the world for the better together.

I love our beautiful blue planet and all of God's amazing creation. It breaks my heart to see when we as humans are affecting it and eachother in negative ways- and usually all for the sake of money or something else selfish or something that can be healed within ourselves like unhealed trauma. If I could, I would cut all carbon emissions from vehicles planes and power plants by using renewable energy, drop every kind of pollution in our air land and oceans such as banning the use of plastics and other non biodegradable materials, reforest our land, conserving and increasing our marine biodiversity and health of our ecosystems, and heal every single persons unhealed childhood trauma wounds that have branched off into numerous problems in the lives of generation after generation and has been so deeply rooted that it subsides within the subconscious in ways people often don't even realize. Unfortunately, in this world you need money to survive, and the cost of living keeps going up. This is one of the biggest issues here. Greed and consumerism combined is not helping the health of humanity and our planet. Sadly, there are harmful chemicals being pumped into our planet's lungs and ultimately then our own from major production of all kinds of stuff and carbon emissions. So much polluted plastic that takes forever to break down and puts marine life and the health of our oceans in danger; and chemicals or bioengineered ingredients we really do not need in our food to extend shelf life to make a few extra bucks causing all kinds of illnesses physical and mental. If everybody (including major corporations and companies) cared more about the health of our irreplaceable planet and stoped caring so much about moneywhich comes from trees- trees that grow on our planet and give us oxygen to breathe and keep us alive; which then contributes to the ever increasing deforestation and the collapse of biodiversity in our ecosystems (when the bees are gone we're all gonna be gone..) or

whoever has the power to make a real change for the planet and humanity as a whole- what's the point of everything if we destroy life on Earth as we know it with all of these silly human activities?

So, you see my friends the problem is not with marijuana. We need to take loving, kind, care of ourselves and much better care of our planet altogether as a species sharing this place, we all call home. One of the ways I take loving kind care of myself in this crazy busy world is taking my CBD supplements which comes from the happy grass and doing yoga or meditating in the forest and just trying to be as decent of a person I can and help others any way I can in my community on the day to day in life, being a productive member of society always recycling and never ever littering and trying to conserve energy any way I can.

Thank you for allowing me to share this with you and thank you for taking the time to read it.

Godspeed.

Docket No. DEA-1362

USCA Case #24-1365 Document #2100970 Filed: 02/17/2025 Page 165 of 214



[EXTERNAL] Fwd: ATT: Cannabis rescheduling urgency

From K. Anderson; Mom. Support Staff. Peer Support Spec. <kellyjaninethequeen@gmail.com>
Date Mon 9/9/2024 10:31 AM
To NPRM <NPRM@dea.gov>

"Docket No. DEA-1362

----- Forwarded message -----

From: K. Anderson; Mom. Support Staff. Peer Support Spec. < kellyjaninethequeen@gmail.com >

Date: Mon, Sep 9, 2024, 8:15 AM

Subject: ATT: Cannabis rescheduling urgency

To: <nprm@dea.gov>

Greetings,

I am writing today to ask for a link to be able to participate virtually in the DEA marijuana rescheduling hearing on December 2nd, but first & foremost, I am asking for your help in filing a motion for this hearing to be held much sooner. The Biden Administration instructed the DEA to perform an expeditious review back in May, & a quarter of a year away is too long of a wait for this review hearing, for homeless children who have transitioned out of foster care into homelessness. This is urgent. My reunified family consists of 3 small children & I... we are depending on current federal marijuana restrictions to be reformed much more quickly, so that we may qualify for the rental assistance we were denied eligibility for, simply because of my honesty on my application about my status as a disabled, working, medical marijuana patient. Please help us! Thank you!

Respectfully Yours,
Kelly Anderson | Medi-Cal Peer Support Specialist
Pronouns: She, her, hers
San Diego County
Kellyjaninethequeen@gmail.com
(760) 556-9939 (call / text)
Family & Peer Support Helpline 1-800-523-5933

If you (or someone you know) are experiencing a mental health, substance use, and/or suicide related crisis, please call 988 to access the free and confidential Suicide & Crisis Lifeline and other crisis support. You can also reach the Lifeline through texting 988 or chatting on 988lifeline.org/chat. For other immediate emergencies, please call 911.

My working day may not be your working day. Please do not feel obligated to reply to this email outside your normal working hours.

Filed: 02/17/2025

9-11-2024

Drug Enforcement Administration, Attn: Hearing Clerk/OALJ

(Mailing Address: 2061 Le Mans Dr. Carrollton, Tx 75006)

Subject: Notice of Appearance Oocket No. DEA -1362

Dear Sir:

Please take notice that _Robert Head, Dr. Corey Burchman, Dr. Darinia Douchi, Victor Bohm will appear in the matter of: Schedules of Controlled Substances: Rescheduling of Marijuana

- Robert Head: In November 2023, and in direct response to the President's October 2022 marijuana directive, I petitioned the DEA to initiate proceedings to (1) deschedule marijuana or, in the alternative, (2) reschedule marijuana to schedules III, IV, or V. In that petition, I raised novel statutory and constitutional challenges to marijuana's scheduling status and the laws and regulations that impede moving marijuana to a less-restrictive CSA schedule (IV or V) and to removing it from the CSA's schedules altogether. I explicitly requested that my petition be joined with any agency action initiated to take up the President's directive to reconsider marijuana's schedule I status.
- To this day, I have heard nothing from DEA with respect to my petition or my request that my petition be joined with the ongoing administrative process to reconsider marijuana's schedule I status. In addition to the arguments and evidence discussed further below, this procedural injury gives me a unique claim to have a right to participate in the upcoming ALJ hearing--one that, to my knowledge, no one else has. I attach my November 2023 rescheduling petition here as Exhibit "Alpha".
- As representative of the veteran community, we believe that moving marijuana to schedule 3 will significantly impact veterans in a positive way by helping with PTSD and Pain. I will be accompanied by three subject matter experts who will provide evidence of how cannabis is helping the veteran community:
 - a. Dr. Corey Burchman: A Navy veteran with fellowships focused in Neuroanesthesiology, Obstetrical Anesthesiology and Ambulatory Anesthesia from Harvard Medical School - Brigham and Women's and Massachusetts General Hospital.
 - b. Dr Darina Douchi: A distinguished disabled veteran and Nebraskalicensed pharmacist with an impressive 25-year tenure in Pharmacy and Healthcare policies.

- c. Victory Bohm: CEO of Balanced Veterans Network, testimonials from veterans who use marijuana.
- Rates of suicide and overdose are much higher among veterans than the US population as a whole. Marijuana is used for pain and ptsd by many veterans. We also know that most of the overdoses are from opioids and other prescription pharmaceuticals that have led to side effects that require further medication (Attached: Exhibit Charlie). Veterans were polled and overwhelmingly agree marijuana should be legal. They find that marijuana reduces the medication they are currently on and find themselves more socially active. Studies have shown that daily opioid dosage has been reduced over 70% in some cases for patients and shows significantly improves quality of life. Currently, the VA cannot prescribe cannabis as an alternate to opioids. SCH3 would allow for research and development of pain medication from cannabis that is much safer to consume and the VA will be allow by law to prescribe it.

SSRIs are over prescribed in the veteran community. Marijuana can help reduce certain medication. SCH 3 will allow for some patients to use Marijuana and still keep their prescription if that prescription is on the SCH2 list. Reducing prescriptions, lowering the opioid dosage, and allowing for a more holistic approach by using cannabis will help reduce our current 22 a day suicide rate.

- a. Dr. Burchman: Treating veterans with PTSD and pain with marijuana is a much safer option than the current pharmacological approach.
- b. Dr. Darina Douchi: Schedule one does not allow for the VA to prescribe marijuana and makes some veterans who use marijuana ineligible to continue schedule 2 prescriptions.
- c. Victor Bohm: CEO of Balanced Veterans Network, who helps veterans with cannabis education, and has testimonies from veteran on their marijuana use and the benefits they have seen correlate with what our SMEs on pain and PTSD have presented.
- Our Position: We believe that veterans should not be penalized or face
 discrimination for choosing to use marijuana over the prescriptions they receive
 from the VA. We believe that rescheduling to Schedule III, IV, V, or descheduling
 will help lower suicide and overdose rates in the veteran community by taking a
 more holistic approach with safer medicine, reducing medications, and improving
 overall wellness through the VA. This cannot be done under Schedule I.
 - There is overwhelming data demonstrating the therapeutic efficacy of cannabis as an analgesic and further evidence of cannabis as an agent of harm reduction, and the substitution effect whereby use of cannabinoids can

- diminish the use of adjunctive agents, such as other analgesics, antidepressants and anti-anxiety meds. (Attached; Exhibit Bravo)
- Rescheduling to Schedule III will allow veterans who test positive for marijuana to still maintain their prescriptions for Schedule II medications. With some form of marijuana being legal in over 35 states, the majority of the veteran population has legal access to marijuana. Most veterans who use marijuana do so for pain and PTSD, which affects 23% of veterans in the VA system.
- 3. Better overall life improvement.
 - a. In a large prospective study on if Cannabis Significantly Reduces the Use of Prescription Opioids and Improves Quality of Life in Authorized Patients. It concluded that "The high rate of cannabis use for chronic pain and the subsequent reductions in opioid use suggest that cannabis may play a harm reduction role in the opioid overdose crisis, potentially improving the quality of life of patients and overall public health."
 - b. Balanced Veterans Network is a 501c3 nonprofit organization consisting of over five thousand members that educates, advocates, and supports access to alternative therapies for veterans and their families. Operation 1620 is the medical cannabis initiative of Balanced Veterans Network. Medical cannabis is a proven, safe, and effective personal health management option for veterans. Medicinal cannabis is an incredibly effective tool for veterans challenged with managing the symptoms of their pain and PTSD as opposed to dangerous narcotics such as opiates and other addictive prescription medications. Over the past five years, Operation 1620 has provided hundreds of veterans access to no cost Medical Marijuana certifications in 33 of the states and territories where cannabis is medically legal. Additionally, Operation 1620 provides Medical Marijuana card fee reimbursements for veterans, as well as mentorship and educational courses.
 - c. American Legion Post 426 issued a resolution to their National Headquarters titled "Support for FDA Breakthrough Therapies for Veteran Suicide Prevention."

All notices to be sent pursuant to this appearance should be addressed to:

Robert Head 2061 Le Mans Dr Carrollton, Texas Respectfully yours, [81 FR 97041, Dec. 30, 2016]

Filed: 02/17/2025

November 15, 2023

Re:

Anne Milgram, Administrator Drug Enforcement Administration Attn: Administrator 8701 Morrissette Drive Springfield, VA 22152

Petition to initiate rulemaking proceedings to deschedule marijuana or, alternatively, to transfer marijuana from schedule I to schedule III, IV, or V, and for joinder in pending rescheduling proceedings.

Dear Administrator Milgram:

The undersigned ("Petitioners") hereby petition to initiate formal rulemaking proceedings for the issuance of an amendment of a rule or regulation under Section 201 of the Controlled Substances Act ("CSA") and to repeal a rule under 5 U.S.C. § 553(e). Specifically, Petitioners seek removal of "marihuana" from schedule I. Petitioners seek a rule removing marihuana from control or, in the alternative, transferring marihuana from schedule I to schedule III, IV, or V.

Consistent with the CSA and U.S. Drug Enforcement Administration ("DEA") regulations, Petitioners attach the following exhibits and incorporate them as part of this petition:

Exhibit A1: The proposed rule in the form Petitioners propose.

Exhibit A2: The alternate proposed rule in the form Petitioners propose.

Exhibit A3: Repealing the definition of "medicinal cannabis" in the form Petitioners propose.

Exhibit B: A statement of the grounds on which Petitioners rely.

Petitioners request that the Administrator promptly notify them of acceptance or nonacceptance of the petition and, if not accepted, the reasons therefor.

Petitioners further request and move that they formally be joined as a party to any marijuana rescheduling proceeding currently pending before DEA, including the pending one

- 2 -

November 15, 2023

Filed: 02/17/2025

publicly referenced by Secretary Becerra, that their grounds and arguments herein be incorporated into such proceedings, they receive notification of joinder, and that they receive all appropriate notices from the agency regarding the progress of the proceedings.

Finally, Petitioners petition and request repeal of 21 C.F.R. § 1318.02(b), to the extent the U.S. Department of Health and Human Services ("HHS") recommendation recently received by DEA concludes that marijuana has a "currently accepted medical use in treatment in the United States," for the reasons stated therein.

Introduction

In more than two-thirds of states, millions use marijuana² in treatment following a recommendation from a licensed physician. Most, if not all, these states have reticulated regimes governing and limiting medical-marijuana use. Every year since 2014, Congress has supported these regimes by approving a spending rider prohibiting the U.S. Department of Justice ("DOJ") from using appropriated funds to interfere with their enforcement. Indeed, no social issue unites more Americans than medical marijuana. Recent polls show that 91% of Americans support medical use under these state-law regimes.³ This level of support holds true among our nations' veterans as well.⁴

And yet, DEA insists marijuana has "no currently accepted medical use in treatment in the United States." Rather than apply the statutory text, DEA claims "currently accepted medical use in treatment in the United States" requires meeting a five-part test that it admits cannot be squared with the statute's plain meaning. Petitioners request that DEA do what the statute commands and remove marijuana from schedule I.

DEA should remove marijuana from the schedules entirely. Across almost half the country, states have opted out of the federal government's failed prohibitionist regime. Millions of Americans, as a result, are using marijuana non-medically and responsibly under regulated regimes. With even more states opting out each year, marijuana and natural THC products have attained a cultural status akin to caffeine, alcohol, and tobacco. Can marijuana be abused? Absolutely. Should it be regulated? Definitely. Because a significant majority of Americans no

See https://www.hhs.gov/sites/default/files/signed-ash-to-dea-letter-marijuana.pdf.

The statutory term for marijuana is "marihuana." In discussion, Petitioners use marihuana and marijuana interchangeably.

³ See https://www.pewresearch.org/fact-tank/2021/04/16/americans-overwhelmingly-say-marijuana-should-be-legal-for-recreational-or-medical-use/

See, e.g., https://www.armytimes.com/veterans/2017/11/02/poll-more-than-90-percent-of-vets-support-medical-marijuana-research/ (over 80% back allowing federal doctors to prescribe).

⁵ See 21 U.S.C. § 812(b)(1)(B).

- 3 -

November 15, 2023

longer consider marijuana a drug of abuse worthy of DEA's attention, however, it no longer has a legitimate place on the CSA's schedules.

Alternatively, DEA should transfer marijuana to schedule III, IV, or V based on scientific evidence related to its abuse potential and dependence risk. Placing it in schedule II alongside far more dangerous and addictive drugs like fentanyl would do nothing to make Americans safer. If anything, it would serve only to undermine the legitimacy of the federal scheduling regime, making it even harder for the federal government to address urgent national crises like opioid abuse effectively.

Respectfully submitted,

Matthewfor

Matthew C. Zorn

Shane Pennington

Counsel for Petitioners Hemp for Victory⁶ and Robert Head

All notices to be sent regarding this petition should be addressed to:

For Hemp for Victory and Robert Head:

Matthew Zorn Yetter Coleman LLP 811 Main St., Ste. 4100 Houston, TX 77002 mzorn@yettercoleman.com

Shane Pennington Porter Wright Morris & Arthur LLP 2020 K Street, NW, Suite 600 Washington, D.C. 20006 spennington@porterwright.com

⁶ Hemp for Victory is a non-profit organization headquartered in Carrolton, TX that focuses on cannabis education and the positive impact of cannabis on the veteran community. *See* https://hemp4victory.info/about-us/.

- 4 -

November 15, 2023

Exhibit A1 – Proposed Rule

We propose the following: removing "marihuana" from schedule I [21 C.F.R. 1308.11(d)(23)].

The following is the proposed rule:

REMOVE: 21 C.F.R. 1308.11(d)(23).

Exhibit A2 – Alternate Proposed Rule

We propose the following: removing "marihuana" from schedule I [21 C.F.R. 1308.11(d)(23)] and placing it in schedule [III, IV, or V].

The following is the proposed rule:

REMOVE: 21 C.F.R. 1308.11(d)(23).

ADD: 21 C.F.R. 1308.[13, 14, 15] schedule [III, IV, V]: "... (f) Hallucinogenic substances. (1) ... (3) Marijuana."

Exhibit A3 - Proposed Rule

The following is the proposed rule:

REMOVE: 21 C.F.R. 1318.02(b)

- 5 -

November 15, 2023

Filed: 02/17/2025

Exhibit B – Statement of Grounds

I. The Schedule I Factors

a. Marijuana has a "currently accepted medical use in treatment in the United States."

As of April 2023, at least 38 states, the District of Columbia, and 4 of 5 territories (Guam, Northern Mariana Islands, Puerto Rico, U.S. Virgin Islands) have legalized medical marijuana. According to the plain and ordinary meaning of "accepted medical use in treatment," marijuana has a currently accepted medical use in treatment in the United States. In addition, because marijuana has an accepted medical use, the U.S. Pharmacopeia is currently in the process of establishing a monograph for cannabis (including marijuana) for medical use.

In the past, to determine whether a drug lacks a "currently accepted medical use in treatment in the United States"—the second required finding for placement in schedule I, see 21 U.S.C. § 812(b)(1)(B)—DEA has applied a five-part test of its own making:

- 1. the drug's chemistry must be known and reproducible;
- 2. there must be adequate safety studies;
- 3. there must be adequate and well-controlled studies proving efficacy;
- 4. the drug must be accepted by qualified experts; and
- 5. the scientific evidence must be widely available.

See 81 Fed. Reg. 53688, 53700 (Aug. 12, 2016) (citing Alliance for Cannabis Therapeutics v. DEA, 15 F.3d 1131, 1135 (D.C. Cir. 1994)). See also, e.g., 86 Fed. Reg. 60,761 at 762 n.5 (Nov. 4, 2021) ("[A] drug cannot be found to have such medical use unless DEA concludes that it satisfies a five-part test[.]").

For at least the reasons stated by the petitioners in Sisley v. DEA (Ex. 1), which Petitioners incorporate here by reference, DEA's five-part test is unlawful. Most prominently, the test interprets § 812(b)(1)(B) in way that renders § 812(b)(1)(C) superfluous—a red flag that its interpretation cannot be right. See, e.g., Gustafson v. Alloyd Co., 513 U.S. 561, 574 (1995) (courts avoid interpretations that "render[] some words altogether redundant"). This third requirement for placing a substance in schedule I expressly demands a finding regarding a substance's safety for use. See 21 U.S.C. § 812(b)(1)(C). Given all this, DEA's insistence that the second requirement (a lack of "currently accepted medical use") must also hinge in part on proof of safety for use makes no sense.

As Judge Watford explained after reviewing petitioners' arguments in Sisley:

[I]n an appropriate case, the Drug Enforcement Administration may well be obliged to initiate a reclassification proceeding for marijuana, given the strength of petitioners' arguments that the agency has misinterpreted the controlling statute by concluding that

-6-

November 15, 2023

Filed: 02/17/2025

marijuana "has no currently accepted medical use in treatment in the United States." 21 U.S.C. § 812(b)(1)(B).⁷

Under any reasonable interpretation of "currently accepted medical use in treatment in the United States" based on the ordinary public meaning of those terms, DEA *must* reschedule marijuana.⁸

First, in more than two-thirds of the country, according to state law, marijuana use in treatment is accepted medical practice. See, e.g., Conant v. McCaffrey, 2000 WL 1281174, at *14 (N.D. Cal. Sept. 7, 2000) (court applying plain and ordinary meaning to conclude that marijuana is a medically acceptable form of treatment in California and seven other states). State law, not DEA preference, determines what is legitimate medical practice in the United States, a reality DEA itself has acknowledged. In the opioid-prescription context, for example, DEA has emphasized that it

does not act as the Federal equivalent of a State medical board overseeing the general practice of medicine. State laws and State licensing bodies ... collectively regulate the practice of medicine. In contrast, the scope of the CSA (and therefore role of DEA) is much narrower.

71 Fed. Reg. 52,716, 52,717 (Sept. 6, 2006). No doubt, the evidence will show that medical professionals have recommended marijuana for their patients under duly enacted state laws. See also, e.g., United States v. Green, 222 F. Supp. 3d 267, 275 (W.D.N.Y. 2016) ("no rational basis to conclude" that marijuana is not being currently used for medical purposes).

United States v. Moore, 423 U.S. 122, 141 (1975) is instructive. There, the Supreme Court explained that "provisions throughout the Act reflect the intent of Congress to confine authorized medical practice within accepted limits." Id. The terms of the CSA reflect a congressional intent to align "accepted medical use" with accepted standards of professional practice as determined by state law. Here, it is accepted medical practice for physicians to recommend marijuana use for treatment of certain conditions, such as ameliorating chemotherapy's side-effects.

Judge Watford is not alone in flagging DEA's misinterpretation of the CSA. At oral argument in *Washington v. Barr*, 925 F.3d 109 (2d Cir. 2019), Judge Rakoff did as well. See https://ww3.ca2.uscourts.gov/decisions (oral argument recording).

Indeed, because the five-part test as it stands is unlawful, we also ask that it be repealed or amended. 5 U.S.C. § 553(e).

See, e.g., https://www.cbsnews.com/news/survey-76-percent-of-doctors-approve-of-medical-marijuana-use/ (New England Journal of Medicine Poll: 76% of votes in favor of the use of marijuana for medicinal purposes); https://www.safeaccessnow.org/survey_majority_of_us_doctors_support_medical_marijuana_legalization (citing polls); https://www.liebertpub.com/doi/10.1089/can.2020.0165 (almost 70% of clinicians believe cannabis has medicinal uses).

- 7 -

November 15, 2023

Filed: 02/17/2025

Second, recognizing that marijuana has a currently accepted medical use, the U.S. Pharmacopeia in September 2022 published a proposed *Cannabis* Species Inflorescence monograph in the Herbal Medicines Compendium. The inclusion of cannabis in the U.S. Pharmacopeia is imminent.¹⁰

These circumstances establish a currently accepted medical use beyond cavil. As discussed in *Sisley*, during congressional hearings, the CSA's drafters explained that "you don't have to be a doctor to find out whether or not it has an accepted medical use in the United States or not" and the issue "is not something that you are going to create research on." An agency memo drafted shortly after the CSA's passage (Ex. 3) underscores the point:

As the situation stands presently, there is no medical use for marihuana in the United States. The Food and Drug Administration has not granted a New Drug Application for its use in medicine; *marihuana is not listed in the United States Pharmacopeia*, the National Formulary, the American Drug Index, 1972, Drugs of Choice, 1972, or Physicians Desk Reference, 1972. In fact, both the United States Dispensatory and Remington's Pharmaceutical Sciences conclude that there is no rational or indispensable therapeutic use for marihuana in modern medicine.

This text, written around the time the CSA was enacted, focuses on the plain meaning of the relevant statutory language and makes the proper § 812(b)(1)(B) inquiry unmistakably clear. See Bostock v. Clayton Cty., Georgia, 140 S. Ct. 1731, 1750 (2020) (the law's ordinary meaning at the time of enactment usually governs). And it does not suggest the five-part test. It instead accounts for evidence establishing acceptance among medical authorities.

In short, the five-part test as an exclusive means to test accepted medical use is unlawful. While FDA approval or satisfying the five-part test clearly suffices to show a currently accepted medical use in treatment, it cannot be *the only* way to make that showing. Here, when more than two-thirds of the states—the traditional and authoritative regulators of the medical practice—have adopted laws specifically allowing a drug to be used to treat specific conditions, DEA has no discretion to ignore the statute's plain text to conclude that marijuana lacks a "currently accepted medical use in treatment in the United States." ¹²

For substantially similar reasons, 21 C.F.R. § 1318.02(b) should be repealed.

Drug abuse control amendments—1970, Hearings, 91st Cong., 2d Sess., on H.R. 11701 and H.R. 13743 (Part 1) at 165 (1970).

DEA's own arguments in *In re: Marijuana Rescheduling* (Ex. 2) further support Petitioners' position. There, DEA emphasized the fact that parties disputed whether states had passed "research statutes" or "treatment statutes." DEA went on to explain that the reason it advocated for the same standards that FDA uses for medical acceptability was because those same standards "permeated themselves into the medical community and part of them have been incorporated into the standards that clinicians use to determine whether a drug has an accepted medical use." *Id.* at 36. In other words, DEA argued that FDA

November 15, 2023

Filed: 02/17/2025

FDA has long recognized state-level use of a substance in treatment as a viable means of demonstrating "currently accepted medical use in treatment in the United States" for purposes of 21 U.S.C. § 812(b)(1)(B). In 1982, for example, FDA concluded that drugs can "obtain[] 'accepted medical use'" for purposes of § 812(b)(1)(B) "by virtue of totally intrastate production and use." 47 Fed. Reg. 28,141, 28,150-51 (June 29, 1982). FDA's longstanding view is especially important in this context because the question of what constitutes "currently accepted medical use in treatment in the United States" implicates FDA's scientific and medical expertise as opposed to DEA's law-enforcement expertise, meaning DEA is statutorily bound to accept its legitimacy. See 21 U.S.C. § 811(b) ("The recommendations of the Secretary [and their delegee, FDA] to the Attorney General [and their delegee, DEA] shall be binding on the Attorney General [and his delegee, DEA] as to such scientific and medical matters ").

On this point, the Supreme Court's decision in *Gonzales v. Oregon* is instructive. 546 U.S. 243, 258 (2006). There, the Court rejected the interpretation of the CSA as authorizing the Attorney General to "declar[e] illegitimate a medical standard for care and treatment of patients that is specifically authorized under state law." *Id.* at 245. Because the CSA refutes the notion that Congress intended to delegate to the Attorney General any authority to make binding judgments regarding the practice of medicine or science, the Court held the Attorney General's views on what constitutes a "legitimate medical purpose" were not authoritative. *Id.*

Addressing this question directly, the Supreme Court emphasized that "[i]n the scheduling context," the CSA requires DEA to yield to FDA's views on scientific and medical matters:

The CSA allocates decision[]making powers among statutory actors so that medical judgments, if they are to be decided at the federal level and for the limited objects of the statute, are placed in the hands of the Secretary. In the scheduling context, for example, the Secretary's recommendations on scientific and medical matters bind the Attorney General. The Attorney General cannot control a substance if the Secretary disagrees. 21 U.S.C. § 811(b). See H.R.Rep. No. 91–1444, pt. 1, p. 33 (1970), U.S. Code Cong. & Admin. News 1970, pp. 4566, 4600 (the section "is not intended to authorize the Attorney General to undertake or support medical and scientific research [for the purpose of scheduling], which is within the competence of the Department of Health, Education, and Welfare").

Id. at 265. In fact, long before *Oregon*, DEA itself acknowledged that it had no delegated authority to make medical judgments or to regulate the practice of medicine, 57 Fed. Reg. at 10,505:

Clearly, the Controlled Substances Act does not authorize the Attorney General, nor by delegation the DEA Administrator, to make the ultimate medical and policy decision as to whether a drug should be used as medicine. Instead, he is limited to

standards serve as a proxy or indirect evidence for what the medical community accepts as having medical use when direct evidence of accepted medical use is not available.

-9-

November 15, 2023

Filed: 02/17/2025

determining whether others accept a drug for medical use. Any other construction would have the effect of reading the word "accepted" out of the statutory standard.

b. There is an accepted safety for use of marijuana under medical supervision.

For similar reasons, there is an accepted safety for use of marijuana under medical supervision. Contemporary evidence (including peer-reviewed clinical research) shows, for example, that marijuana use is generally safe. ¹³ Such research also does not associate medical-marijuana use with severe adverse events, even among those with mental disorders. ¹⁴

Indeed, marijuana not only can be safely used under medical supervision, but in many instances, doctors recommend marijuana over approved pharmaceuticals as a safer, less-addictive alternative. For example, there is "substantial evidence that cannabis is an effective treatment for chronic pain in adults." Some states permit marijuana recommendations in lieu of opioid prescriptions. There is substantial evidence that medical marijuana can substitute for opioid-based pain medications. ¹⁶

c. Marijuana does not have a high potential for abuse.

In studies ranking the relative harmfulness of drugs, marijuana consistently ranks below drugs in schedules I and II.

In a study by Bonnet, Udo et al. (2020) entitled "Ranking the Harm of Psychoactive Drugs Including Prescription Analgesics to Users and Others-A Perspective of German Addiction

See, e.g., Bonn-Miller, Marcel O et al. "The short-term impact of 3 smoked cannabis preparations versus placebo on PTSD symptoms: A randomized cross-over clinical trial." *PloS one* vol. 16,3 e0246990. 17 Mar. 2021

See, e.g., Hoch E, Niemann D, von Keller R, Schneider M, Friemel CM, Preuss UW, Hasan A, Pogarell O. How effective and safe is medical cannabis as a treatment of mental disorders? A systematic review. Eur Arch Psychiatry Clin Neurosci. 2019 Feb;269(1):87-105. doi: 10.1007/s00406-019-00984-4. Epub 2019 Jan 31. Erratum in: Eur Arch Psychiatry Clin Neurosci. 2019 Apr 5;: PMID; 30706168; PMCID; PMC6595000.

National Academies of Sciences, Engineering, and Medicine, The Health Effects of Cannabis and Cannabinoids: The Current State of Evidence and Recommendations for Research at 87-90 (2017); Romero-Sandoval, E Alfonso et al. "Cannabis and Cannabinoids for Chronic Pain." Current rheumatology reports vol. 19,11 67. (Oct. 5, 2017) (Exhibit C) (concluding that "scientific evidence presented demonstrates that inhaled cannabis is clinically useful for the treatment of chronic (neuropathic) pain, and seems to be safe and tolerable for long-term use under medical supervision").

E.g., Reiman A, Welty M, Solomon P. Cannabis as a Substitute for Opioid-Based Pain Medication: Patient Self-Report. Cannabis Cannabinoid Res. 2017 Jun 1;2(1):160-166. doi: 10.1089/can.2017.0012. PMID: 28861516; PMCID: PMC5569620.

November 15, 2023

Filed: 02/17/2025

Medicine Experts," for example, 30 substances were ranked according to harm to users and others. ¹⁷ Cannabis ranked below schedule I and II drugs such as heroin and methamphetamine and alongside schedule III drugs such as benzodiazepines and ketamine. Common experience dictates that marijuana has fewer relative harms than opioids. ¹⁸ Compared to benzodiazepines, marijuana also presents a lower potential for abuse and less risk of dependence. Indeed, research suggests medical marijuana can be used to discontinue benzodiazepine use. ¹⁹

Other evidence underscores marijuana's low abuse potential. For example, Dr. Volkow recently stated that to her knowledge, there's "no evidence" that occasional adult marijuana use has harmful effects. This DEA cannot ignore: Dr. Volkow currently directs the National Institute of Drug Abuse and is an expert in marijuana research having authored dozens of articles on marijuana use, including Zehra, Amna et al. (2018) entitled "Cannabis Addiction and the Brain: a Review" and Volkow, Nora D et al. (2016) entitled "Effects of Cannabis Use on Human Behavior, Including Cognition, Motivation, and Psychosis: A Review." ²¹

d. 21 U.S.C. § 811(d)(1) does not limit DEA's authority.

For at least the reasons stated by the petitioners in *Sisley v. DEA* (Ex. 1), section 811(d)(1) is unconstitutional. Petitioners hereby incorporate Shane Pennington & Matthew Zorn, *The Controlled Substances Act: An International Private Delegation That Goes Too Far*, 100 Wash. U. L. Rev. (2023) (https://wustllawreview.org/2023/05/19/the-controlled-substances-act-an-international-private-delegation-that-goes-too-far/) by reference.

Also, as noted by the agency, even if § 811(d)(1) does apply, DEA has discretion to control marijuana in schedule III, IV, or V, and simultaneously amend its regulations to require a permit to import or export marijuana, as it did with Epidiolex. 83 Fed. Reg. 48,950 (Sept. 28, 2018).

Bonnet, Udo et al. "Ranking the Harm of Psychoactive Drugs Including Prescription Analgesics to Users and Others-A Perspective of German Addiction Medicine Experts." Frontiers in psychiatry vol. 11 592199. 26 Oct. 2020, doi:10.3389/fpsyt.2020.592199.

Lake, Stephanie et al. "Evidence shows that cannabis has fewer relative harms than opioids." CMAJ: Canadian Medical Association journal = journal de l'Association medicale canadienne vol. 192,7 (2020): E166-E167.

Purcell, Chad et al. "Reduction of Benzodiazepine Use in Patients Prescribed Medical Cannabis." Cannabis and cannabinoid research vol. 4,3 214-218. 23 Sep. 2019.

Zehra, Amna et al. "Cannabis Addiction and the Brain: a Review." Journal of neuroimmune pharmacology: the official journal of the Society on NeuroImmune Pharmacology vol. 13,4 (2018): 438-452.

Volkow, Nora D et al. "Effects of Cannabis Use on Human Behavior, Including Cognition, Motivation, and Psychosis: A Review." *JAMA psychiatry* vol. 73,3 (2016): 292-7. doi:10.1001/jamapsychiatry.2015.3278

November 15, 2023

Filed: 02/17/2025

II. DEA Should Deschedule Marijuana.

Section 811(b) provides that if the Attorney General determines that the eight-factors listed in 811(c) and "all other relevant data" constitute "substantial evidence that the drug or other substance should be removed entirely from the schedules," then the Attorney General "shall initiate proceedings for control or removal." In the case of marijuana, substantial evidence outside of the Section 811(c) factors shows that marijuana should be removed entirely from the schedules and regulated by the states.

Not all drugs of abuse—even addictive ones—are controlled. Caffeine has addictive properties that may lead to physical dependence. ²² Caffeine intoxication may result in tachycardia, vomiting, cardiac arrhythmias, seizures, and in extreme doses, death. ²³ Caffeine use disorder is a problematic pattern of caffeine consumption characterized by a persistent desire to cut down or control use of the substance along with unsuccessful efforts to do so despite problems caused or worsened by caffeine. ²⁴ But caffeine is not scheduled because it is a commonly accepted drug. Most people who use caffeine do so safely every day. Many use caffeine socially, such as by drinking coffee in a café. Some use caffeine as a drug to start their day.

As of 2023, marijuana has achieved a cultural status similar to caffeine and tobacco. Almost 16% of Americans smoke marijuana²⁵—more than the number of Americans that smoke tobacco cigarettes.²⁶ The vast majority of marijuana users use marijuana safely with no effects more serious than caffeine. Marijuana is used a social drug. In states where marijuana is legal, there are marijuana cafés or lounges. Marijuana can also be used as a drug before bedtime for sleep. For these reasons, nearly 60% of Americans believe marijuana should be removed from control.²⁷

See, e.g., Gilliland K, Bullock W. Caffeine: a potential drug of abuse. Adv Alcohol Subst Abuse. 1983-1984 Fall-Winter;3(1-2):53-73. PMID: 6391103.

De Sanctis V, Soliman N, Soliman AT, Elsedfy H, Di Maio S, El Kholy M, Fiscina B. Caffeinated energy drink consumption among adolescents and potential health consequences associated with their use: a significant public health hazard. Acta Biomed. 2017 Aug 23;88(2):222-231. doi: 10.23750/abm.v88i2.6664. PMID: 28845841; PMCID: PMC6166148.

Addicott MA. Caffeine Use Disorder: A Review of the Evidence and Future Implications. Curr Addict Rep. 2014 Sep;1(3):186-192. doi: 10.1007/s40429-014-0024-9. PMID: 25089257; PMCID: PMC4115451.

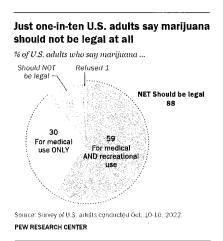
https://news.gallup.com/poll/284135/percentage-americans-smoke-marijuana.aspx.

https://www.cdc.gov/tobacco/data_statistics/fact_sheets/adult_data/cig_smoking/index.htm.

https://www.pewresearch.org/fact-tank/2022/11/22/americans-overwhelmingly-say-marijuana-should-be-legal-for-medical-or-recreational-use/ft_2022-11-22 marijuana 01a/.

Document #2100970

November 15, 2023



Equally important, marijuana is treated differently from other drugs of abuse listed in the CSA. Every year Congress prohibits DOJ from spending funds to interfere with state medical marijuana programs. The Attorney General recently confirmed that marijuana enforcement continues to be a low priority for DOJ²⁸—indeed, it is hard to see how DEA could summon the resources necessary to faithfully enforce the CSA as long as marijuana remains a controlled substance. And the President recently pardoned those convicted of simple marijuana possession.

Removing marijuana from the CSA does not mean that the law no longer sees marijuana as a drug that can be abused. The absence of caffeine or tobacco from the CSA's schedules certainly does not mean those drugs cannot be and are not abused. Nor would descheduling marijuana mean that marijuana should not—or would not—be regulated. Rather, descheduling would simply align federal marijuana law with what is by now beyond manifest: for marijuana, the CSA is no longer the appropriate regulatory framework; and DEA is no longer an appropriate regulator. ²⁹

III. Alternatively, Marijuana Should be Rescheduled.

Placement in schedule I "does not appear to flow inevitably from lack of a currently accepted medical use." See Nat'l Org. for Reform of Marijuana L. (NORML) v. DEA, 559 F.2d 735, 748 (D.C. Cir. 1977). "[T]he structure of Section 202(b) contemplates balancing of medical usefulness along with several other considerations, including potential for abuse and danger of dependence." Id.

https://www.judiciary.senate.gov/imo/media/doc/QFR%20Responses%202-28.pdf.

Many other abused drugs are not scheduled, such as nutmeg (routinely used in cooking) and nitrous oxide (routinely used as whipped cream chargers). Both have substantial non-medical uses and are sold by non-medical providers. The disruption that would be caused by scheduling these substances is "other relevant data" that weighs strongly against control.

- 13 -

November 15, 2023

Filed: 02/17/2025

As noted above, marijuana has a currently accepted medical use in treatment in the United States. But even if it did not, balancing of medical usefulness along with other considerations would justify downscheduling. In particular, marijuana has a low physical/psychological dependence risk compared to other drugs such as fentanyl.

a. Schedule V or IV

A drug in schedule V has a low potential for abuse and limited physical dependence or psychological dependence relative to the drugs in schedule IV. Compared to benzodiazapenes in schedule IV, marijuana has a low potential for abuse and lower psychological dependence. Marijuana use may produce some level of dependence, and cessation of use may produce withdrawal symptoms.³⁰ But dependence associated with marijuana use and marijuana withdrawal is far less significant than benzodiazepine dependence and benzodiazepine withdrawal.³¹

b. Schedule III

A drug in schedule IV has a low potential for abuse and limited physical dependence or psychological dependence relative to the drugs in schedule III. As discussed above, marijuana does not have the same potential for abuse as drugs in schedule II such as methamphetamine, cocaine, and fentanyl. Indeed, some evidence suggests cannabis use is associated with a reduced risk of opioid exposure.³²

IV. Conclusion

The Administration has stated that "science will guide" the decision to reschedule marijuana. As important, the decision must be guided by law. Marijuana's current classification under the CSA as a schedule I substance is legally infirm. For this reason, it must be descheduled or, alternatively, rescheduled.

See, e.g., Connor JP, Stjepanović D, Le Foll B, Hoch E, Budney AJ, Hall WD. Cannabis use and cannabis use disorder. Nat Rev Dis Primers. 2021 Feb 25;7(1):16. doi: 10.1038/s41572-021-00247-4. PMID: 33627670; PMCID: PMC8655458.

See Baandrup L, Ebdrup BH, Rasmussen JØ, Lindschou J, Gluud C, Glenthøj BY. Pharmacological interventions for benzodiazepine discontinuation in chronic benzodiazepine users. Cochrane Database Syst Rev. 2018 Mar 15;3(3):CD011481. doi: 10.1002/14651858.CD011481.pub2. PMID: 29543325; PMCID: PMC6513394.

See, e.g., Socías ME, Choi J, Lake S, Wood E, Valleriani J, Hayashi K, Kerr T, Milloy MJ. Cannabis use is associated with reduced risk of exposure to fentanyl among people on opioid agonist therapy during a community-wide overdose crisis. Drug Alcohol Depend. 2021 Feb 1;219:108420. doi: 10.1016/j.drugalcdep.2020.108420. Epub 2020 Dec 17. Erratum in: Drug Alcohol Depend. 2021 Apr 1;221:108547. PMID: 33342591; PMCID: PMC8006801.

Exhibit: Bravo

Cannabis and Harm Reduction: Exploring Substitution Effects and the Decline in

Therapeutics Use

C Burchman, MD

Cannabis, particularly its cannabinoids, has garnered attention for its therapeutic potential in recent years. As more jurisdictions decriminalize or legalize cannabis use, its role in harm reduction strategies has come into focus. One of the most significant impacts of cannabis-based interventions is their substitution effect, where cannabis is used as an alternative to more harmful substances, including prescription medications such as analgesics (painkillers), anxiolytics (anti-anxiety medications), and antidepressants.

Cannabis and Harm Reduction

Harm reduction refers to strategies aimed at minimizing the negative consequences of substance use rather than insisting on complete abstinence. Cannabis fits into this framework by offering a less harmful alternative to more dangerous substances such as opioids, alcohol, and prescription medications with high addiction potential. In some contexts, particularly where opioid use is prevalent, cannabis has been seen as a tool to reduce the public health burden by helping individuals reduce or cease opioid use.

Cannabinoids, the active compounds in cannabis, interact with the body's endocannabinoid system, which is involved in regulating pain, mood, and anxiety. Cannabidiol (CBD) and tetrahydrocannabinol (THC) are the most researched cannabinoids for these effects. These compounds have been shown to have analgesic, anxiolytic, and antidepressant-like effects, making them viable alternatives for patients who rely on pharmaceutical interventions for these issues.

Substitution Effect of Cannabis

The substitution effect refers to the phenomenon where one substance replaces another in an individual's consumption pattern. In the case of cannabis, its legalization or medical adoption can lead to a reduction in the use of other, often more harmful, substances. Several studies have pointed to the potential of cannabis as a substitute for prescription drugs, particularly in the areas of pain management, anxiety, and depression.

1. Analgesics (Painkillers)

Cannabis has been shown to be effective in managing chronic pain conditions, particularly in cases where traditional analgesics such as opioids are prescribed. With the opioid crisis continuing to devastate many regions, cannabis offers a safer alternative. Opioids are highly addictive and can lead to overdose, while cannabis has a much lower risk of dependency and no known cases of fatal overdose. Patients using medical cannabis for chronic pain have

reported decreased reliance on opioids, with some studies showing a significant drop in opioid prescriptions in states where medical cannabis is legal.

2. Anxiolytics (Anti-Anxiety Medications):

Benzodiazepines, such as Xanax and Valium, are commonly prescribed for anxiety disorders but come with high risks of dependence and withdrawal symptoms. Cannabidiol (CBD), a non-psychoactive cannabinoid, has been studied for its anxiolytic properties, with evidence suggesting it can reduce symptoms of generalized anxiety disorder and social anxiety without the risks associated with benzodiazepines. As a result, patients are increasingly substituting their anxiolytics with cannabis, particularly CBD-rich strains.

3. Antidepressants:

Cannabis has also been investigated for its potential in treating mood disorders. Depression is commonly treated with selective serotonin reuptake inhibitors (SSRIs), which may have side effects such as weight gain, sexual dysfunction, and emotional blunting. Some users have turned to cannabis, reporting improvements in mood and a reduction in the use of antidepressants. While the research is still in its infancy, preliminary studies suggest that cannabinoids may help modulate mood through their interaction with the endocannabinoid system and serotonin receptors.

Decline in Use of Other Therapeutics

As cannabis becomes a more accepted form of treatment, the use of certain pharmaceuticals has declined. States and countries with medical cannabis programs have reported reductions in prescriptions for opioids, benzodiazepines, and antidepressants. For instance, a 2018 study published in *JAMA Internal Medicine* found that opioid prescriptions dropped significantly in U.S. states with medical cannabis laws. Similar trends have been noted with other psychotropic medications, suggesting that cannabis could serve as an effective harm reduction tool by reducing dependency on more harmful or addictive substances.

Conclusion

Cannabis holds significant promise as part of a harm reduction strategy, particularly through its substitution effect, where it replaces more harmful substances like opioids, benzodiazepines, and certain antidepressants. By providing a safer alternative to these medications, cannabis can reduce the risks associated with addiction, overdose, and dependency, while still offering therapeutic benefits. However, more research is needed to fully understand its efficacy across different populations and conditions, as well as to establish guidelines for safe and effective use. As the stigma around cannabis continues to fade and its medical potential becomes clearer, it may serve as a vital tool in reducing the public health burden of traditional pharmaceuticals.

Exhibit: Charlie

Cannabis and Pain Control

C Burchman, MD

Cannabis, particularly its active compounds called cannabinoids, has gained increasing attention for its potential as an analgesic, or pain-relieving agent. Two of the most studied cannabinoids are tetrahydrocannabinoi (THC) and cannabidiol (CBD), both of which interact with the body's endocannabinoid system (ECS) to modulate various physiological processes, including pain perception.

Mechanism of Action

The ECS plays a critical role in maintaining homeostasis, or balance, in the body. It consists of endocannabinoids (natural molecules similar to cannabinoids), receptors (CB1 and CB2), and enzymes that synthesize and degrade these molecules. When cannabis is consumed, THC binds primarily to CB1 receptors, which are abundant in the central nervous system, including the brain and spinal cord. This interaction helps modulate pain signaling and reduce the perception of pain.

CBD, on the other hand, does not bind directly to CB1 or CB2 receptors but affects them indirectly. It also interacts with other pain-regulating systems, such as the serotonin receptors, contributing to pain relief without the psychoactive effects associated with THC. CBD may also reduce inflammation, a key contributor to chronic pain in conditions like arthritis and multiple sclerosis.

Types of Pain Addressed by Cannabis

Cannabis has shown promise in treating a variety of pain types:

- 1. Chronic Pain: Long-term conditions such as fibromyalgia, arthritis, and neuropathic pain (nerve damage-related pain) often cause chronic discomfort. Traditional analgesics, like opioids, can be effective but come with significant side effects, including addiction. Cannabis, especially CBD-rich formulations, has been reported to reduce chronic pain without the risk of dependency.
- 2. Neuropathic Pain: This type of pain results from damage to the nerves and is difficult to treat with standard pain medications. Neuropathic pain is common in conditions like diabetes, multiple sclerosis, and chemotherapy-induced neuropathy. Studies suggest that cannabis can reduce neuropathic pain by affecting both the CB1 and CB2 receptors, which regulate pain signaling pathways in the nervous system.

- 3. Inflammatory Pain: Inflammation is a common source of pain in conditions such as rheumatoid arthritis, Crohn's disease, and other autoimmune disorders. CBD has demonstrated significant anti-inflammatory properties, which contribute to its ability to reduce pain. By decreasing the production of inflammatory molecules like cytokines, cannabis helps alleviate the pain associated with inflammation.
- 4. Cancer Pain: Cannabis is also increasingly used in cancer care to help manage pain, particularly when caused by the cancer itself or its treatments, such as chemotherapy. While not a cure, cannabis can help reduce pain and improve quality of life for cancer patients, without the risk of opioid addiction.

Advantages Over Traditional Analgesics

One of the key advantages of cannabis as an analgesic is its potential to reduce reliance on opioids, which are commonly prescribed for pain but have high addiction potential. In regions where medical cannabis is available, some studies have noted a decrease in opioid prescriptions and overdose deaths, suggesting that cannabis may serve as a safer alternative for pain management.

Additionally, cannabis is generally well-tolerated, with fewer severe side effects compared to many pharmaceuticals. Side effects such as mild sedation, dry mouth, and short-term memory impairment are often dose-dependent and can be managed by adjusting the dose or choosing strains with higher CBD content.

Conclusion

Cannabis offers a multi-faceted approach to pain management through its interaction with the endocannabinoid system and its ability to modulate various neurotransmitters involved in pain perception. While more research is needed to fully understand its long-term efficacy and safety, current evidence supports its role as an effective analgesic, particularly for chronic, neuropathic, and inflammatory pain. Its potential to reduce dependence on opioids further strengthens the case for its use in pain management.

Jim Fricke 2609 Leslie Dr NE Atlanta, Ga 30345 JimFricke@JimFricke.com 404.434.5473 9.11.2024

Administrator
Drug Enforcement Administration

Subject: Request to Speak at Hearing on Rescheduling Cannabis

Dear Administrator,

I am writing to request the opportunity to speak at the upcoming hearing on December 2, 2024, regarding the rescheduling of cannabis from Schedule I to Schedule III. I have been actively involved in the legal cannabis industry for nearly a decade. Prior to this, I served as President of an oilfield company, built and sold a business, and completed a postgraduate degree. My career has evolved into a commitment to the cannabis industry, where I now focus on post-harvest chemovar expertise with the goal of using cannabis to heal the very communities it was once used to harm.

My experience includes owning a dispensary and cultivation operation in Colorado, setting up solventless processing in Humboldt County, California with Frenchy Cannoli, and serving as Director of Cannabis Operations for the largest cannabis farm in the world. I am deeply invested in the potential of cannabis to drive community healing through social equity, particularly for Black, Brown, and Native communities that have been disproportionately impacted by the criminalization of cannabis.

I strongly advocate for the release of all non-violent cannabis offenders from the justice system. Furthermore, I believe that legacy farmers and distributors should receive compensation for the impact of the War on Drugs through social equity grants and loans, ensuring they have the support needed to thrive in the legal market.

I appreciate your consideration of my request to speak at this important hearing, and I look forward to contributing to this critical dialogue on the future of cannabis policy.

Sincerely,

Jim Fricke Owner The Plant Counsel

(City and State) Ontario, Oregon

(Date) Thursday, September 12, 2024 Drug Enforcement Administration, Attn: nprm@dea.gov Hearing Clerk/OALJ (Mailing Address) 401 SE 18th Ave, Ontario Oregon, 97914 Subject: Notice of Appearance Dear Sir: Please take notice that ___Daniel Kyle_ ____ (Name of person) will appear in the matter of: ____Rescheduling of cannabis _21 CFR Part 1301 [Docket No. DEA-1362] RIN 1117-AB77 (Identification of the proceeding). (A) (State with particularity the interest of the person in the proceeding.). To bring to notice of the DEA Issues important to the constitutionality of cannabis regarding medicinal, spiritual and civil use. (B) (State with particularity the objections or issues, if any, concerning which the person desires to be heard.). The current scheduling of cannabis and it's conflict with both constitutional and scientific values. The subjugation of freedom of religion. The disastrous effects on society due to prohibition. (C) (State briefly the position of the person with regard to the particular objections or issues.). I am a medicinal cannabis card holder who works often in a state which upholds prohibition. I have first hand experienced both sides of the coin and dedicate my life to fight for freedom, as I have served this nation as a United States Marine. I affirm the proposal to move to Schedule 3 but I stand for complete descheduling of cannabis as it is a matter of religious liberty, civil rights and freedom, and a very powerful medicine which could prevent thousands of deaths each year through direct and indirect access to legal cannabis. All notices to be sent pursuant to this appearance should be addressed to: (Name) Daniel Kyle (Street Address) 401 SE 18th Ave

Respectfully yours,

(Signature of Person)

[81 FR 97041, Dec. 30, 2016]

USCA Case #24-1365 Document #2100970 Filed: 02/17/2025 Page 190 of 214



[EXTERNAL] Docket No. DEA-1362

From Grayson Lichtenthaler <graysonlichtenthaler@gmail.com>
Date Thu 9/12/2024 3:09 PM
To NPRM <NPRM@dea.gov>

Hi, my name is Grayson Lichtenthaler. I am a cannabis worker and union representative for UFCW 770 in California, reaching out to inquire about the public hearing regarding cannabis rescheduling set for December 2nd, 2024 per Docket No. DEA-1362. I saw information online on how to express interest in participating in the public hearing and just had some additional questions as to what exact information to submit. I've been in the cannabis industry for nearly 6 years now, and seeing as this rescheduling will not only affect my livelihood, but also those of my Union Brothers, Sisters, and Siblings, I would love the opportunity to provide insight from a cannabis worker's perspective to the pros and cons of a reclassifying to Schedule 3. Any additional information would be greatly appreciated. Thank you very much for your time and help.

-Grayson Lichtenthaler hc/him/his 

[EXTERNAL]

From Joshua Taylor <jtayt7@gmail.com>
Date Thu 9/12/2024 11:20 PM
To NPRM <NPRM@dea.gov>

My name is Joshua taylor,

I am just a average Joe however I also have a story if addiction and one where if I had medical Marijuana I would have never gone through. This hearing is huge I need to be there to testify My story. Just a quick testimony is all ask. My email is jtayt7@gmail.com

USCA Case #24-1365 Document #2100970 Filed: 02/17/2025 Page 192 of 214



[EXTERNAL] A former LEO's interest in DEA-1362

From vwjustin@gmail.com <vwjustin@gmail.com>
Date Thu 9/12/2024 7:40 AM
To NPRM <NPRM@dea.gov>

To whom it may concern:

I would like to take a minute to thank you for taking the time to read this letter. I am reaching out in regards to Docket No. DEA-1362. I understand that the cut-off date has passed, but unfortunately, I have only recently become aware of it. I am hoping that I could possibly be placed on a waitlist in case of any cancellations.

I am a former police officer whose career was ended due to an injury. After undergoing surgery, I have been left with a significant amount of residual pain. Additionally, I suffer from a very painful disability known as Ankylosing Spondylitis.

For many years, I believed that cannabis had no medical benefits. However, faced with the prospect of using opioids for pain management, I refused to become another statistic in the opioid epidemic. I would like to discuss how law enforcement officers are often prescribed opioids and can become addicted. According to multiple sources, LEO's are 2 to 3 times more likely to develop an opioid addiction than civilians. Out of desperation, I registered for the medical cannabis program in my state. Despite having the legal ability to purchase cannabis, I initially had reservations. After months of doubt, I reached a point where I could no longer endure the pain I was experiencing. Sadly, I had considered giving up on life. The pain was unbearable. Despite undergoing several rounds of physical therapy for my injury and receiving treatment from the #1 hospital in the country for rheumatology, I still struggle to get through each day. I use the term "suffer" because I have had to discontinue my cannabis use for employment purposes.

Nothing that has been tried for me has been as effective as cannabis, and I would like to share my story, for what it's worth. I believe that hearing from someone who once enforced cannabis laws but, has used it for medical purposes could provide valuable insight. I have found that through the use of cannabis, I can continue to be a productive member of society. I am currently employed by the Baltimore Police Department and the Department of Defense as an engineer in training until I complete my B.S. degree with the University of Maryland, where I maintain a GPA of 3.5 or higher. I believe that my credentials, achievements, and continued success demonstrate that THC use does not prevent one from being a valuable member of society.

Thank you for your time and consideration.

Justin J. Taylor

September 12, 2024

Drug Enforcement Administration, Attn: Hearing Clerk/OALJ

Administrator,

8701 Morrissette Drive

Springfield, Virginia 22152

Dear Sir,

Please take a notice that Wei He, Ph.D. will appear in the matter of Docket No. DEA-1362 on December 2nd, 2024.

- A. I have witnessed many harms caused by Marijuana firsthand.
- B. I object to the rescheduling of Marijuana from the Controlled Substance I to III.
- C. Today's marijuana and marijuana-containing products are very different from the past, and have resulted in many mental health issues from psychosis, paranoid, and hallucination.....Any benefit of Marijuana is anecdotal without rigorous scientific evaluation and without FDA-regulated clinical trials. Finally, Marijuana is a proven gateway drug!

All notices to be sent pursuant to this appearance should be addressed to

Wei He, Ph.D. 2002 Kestral Circle Audubon, PA 19403

Respectively yours

Wei He, Ph.D.

CERTIFICATE OF FORMATION OF WEICARES INNOVATION LLC

FIRST: The name of the limited liability company is Weicares Innovation LLC.

SECOND: The address of its registered office in the State of Delaware is 1013 Centre Road, Suite 403S in the City of Wilmington, County of New Castle, 19801. The name of its Registered Agent at such address is Registered Agents Legal Services, LLC.

THIRD: The purpose of the limited liability company shall be to engage in any lawful act or activity for which a limited liability company may be formed under the Limited Liability Company law of the State of Delaware.

FOURTH: The limited liability company shall have perpetual existence.

FIFTH: Management of the limited liability company is vested in the member(s) in accordance with their ownership interests, unless this is varied by the operating agreement. A limited liability company member may not assign, either wholly or partially, the right to participate in management without the written consent of all limited liability company member(s) or as permitted by the operating agreement. From this day hence, the undersigned has fulfilled the duties of Organizer and relinquishes all further duties to the initial Member(s) of Weicares Innovation LLC. The initial member(s) of the limited liability company shall be:

Wei He, Ph.D. 2002 Kestral Circle Audubon, PA 19403

SIXTH: The name and mailing address of the person forming this limited liability company at the instruction of its member(s) is as follows:

Laura Kash 1013 Centre Road, Suite 403S Wilmington, DE 19801

IN WITNESS WHEREOF, the undersigned has executed this Certificate of Formation of Weicares Innovation LLC on this twenty-second day of July, 2024.

Wei He Organizer

Certificates - Certificate of Formation - Member M (24)

Wei He, Ph.D.

USCA Case #24-1365 Document #2100970 Filed: 02/17/2025 Page 196 of 214



[EXTERNAL] Cannabis Rescheduling Hearing DEA-1362

From Jordan Zito <zito.jordan@yahoo.com>

Date Sat 9/14/2024 11:21 PM

- To NPRM < NPRM@dea.gov>

Pursuant to Docket No. DEA-1362 RIN 1118-AB77; I, Jordan Christopher Zito, would like to electronically submit an originally authored document pertaining to the matter because I cannot physically attend; and I do not know whether the hearing will be publicly available otherwise.

I would like to address Definition making, along with rulemaking if I may, as well as Standards in cidals, metals, whether heavy or light, plasma in product; Lysol's, CFC's, HFC's, propellants, un, and, or, non cured seed oils, Latex, Nitrile, Urethane, and other clear, though not Clear additives, as well as difficulty levels in Sealants, which I would prefer be prohibited and unlawful, though, Sealers and differentiating mandatory disclosures for pastes, glues, adhesives, though not adherents as well as Vaccination disclosures branded somehow.

I will email the document prior to the end date posted on the Federal Register. I have 8 panels in my in-ground container Unit which all touch different parts of soils which carry about 2,000 metric tonnages of VOC solvency. It is not cheap, nor inexpensive to safely do Purely based upon available clearinghouse products in order to create a Schedule with material Facts which V2X cannot penetrate regardless of mass congregation.

Because legalization, and lawful Statutory authorities does not equal total decriminalization nor immunity without specifics (National Specifications) adhered to.

<u>Yahoo Mail: Search, Organize, Conquer</u>

USCA Case #24-1365 Document #2100970 Filed: 02/17/2025 Page 197 of 214

September 16, 2024

Drug Enforcement Administration,

Attn: Administrator- DEA Federal Register Representative/DPW- Hearing Clerk/OALJ

8701 Morrissette Drive, Springfield, Virginia 22152.

Subject: Request for Hearing

Dear Sir:

The undersigned Panacea Plant Sciences C/O David Heldreth hereby requests a hearing in the matter of: DEA rule proposal: Schedules of Controlled Substances: Rescheduling of Marijuana also identified as Docket No. DEA-1362 and A.G. Order No. 5931-2024.

(1) state with particularity the interest of the person in the proceeding; (2) state with particularity the objections or issues concerning which the person desires to be heard; and (3) state briefly the position of the person with regard to the objections or issues.

Panacea Plant Sciences would like to verify standing in the rule-making by asserting that our company:

- 1.) is currently not licensed by the DEA.
- 2.) has research, IP and patent filings that incorporate marijuana, cannabis, THC and related items which under the rule-making would be changed to a new schedule. This change in schedule has the possibility of lowering the valuation of patents and other IP which our company has. As such we will be heavily impacted by this process and rule-making.
- 3.) PPS and David Heldreth are the only public parties with experience in all 3 of the drug scheduling hearings that have occurred since 2020, regarding DOI, DOC and the 5 tryptamines. We have extensive knowledge and history with scheduling proceedings and are the most experienced group in the country in such hearings. PPS should likewise be selected for the hearing.
- 4.) PPS will be harmed if marijuana is moved into Schedule 3 instead of being de-scheduled and will be disadvantaged compared to those companies and businesses that have schedule 3 licensing. Rather than schedule 3, marijuana should be de-scheduled, in order to give PPS access.

Now in regards to the current rule-making, let us begin:

A) To start there are apparent errors in the rulemaking process, in that the DEA did not consult with tribal governments as required under Executive Order 13175.

The rulemaking references active Executive Order 13175 - Consultation and Coordination with Indian Tribal Governments – however, it asserts that no such consultation with tribal governments is necessary, or as stated directly below:

"This proposed rule does not have tribal implications warranting the application of E.O. 13175.

It does not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes."

This statement is incorrect as this rulemaking will change the status of a substance under federal law from Schedule 1 to Schedule 3 it will then as such require changes to tribal law enforcement, tribal health care via independent or Indian Health Services, and other programs. Reservations are regulated as federal lands and many tribal law codes reference federal law and the Controlled Substances Act. As such the current rulemaking will create a situation in which tribal governments and law enforcement will be required to train law enforcement on the new laws and this alone will impose direct costs on tribal entities and governments. Additionally, the costs of any enforcement of these new laws incurred from arrests, testing, jailing, etc. which falls on tribal governments again represent burdens and reasons for the DEA/Department of Justice to conduct a tribal consultation prior to rulemaking as is required under EO 13175. From the text:

"To the extent practicable and permitted by law, no agency shall promulgate any regulation that has tribal implications, that imposes substantial direct compliance costs on Indian tribal governments, and that is not required by statute, unless:

- (1) funds necessary to pay the direct costs incurred by the Indian tribal government or the tribe in complying with the regulation are provided by the Federal Government; or
- (2) the agency, prior to the formal promulgation of the regulation,
- (A) consulted with tribal officials early in the process of developing the proposed regulation;
- (B) in a separately identified portion of the preamble to the regulation as it is to be issued in the **Federal Register**, provides to the Director of OMB a tribal summary impact statement, which consists of a description of the extent of the agency's prior consultation with tribal officials, a summary of the nature of their concerns and the agency's position supporting the need to issue the regulation, and a statement of the extent to which the concerns of tribal officials have been met; and
- (C) makes available to the Director of OMB any written communications submitted to the agency by tribal officials."

Additionally, under the current DOJ tribal consultation policy, the DEA and DOJ are tasked to not narrowly define when it is necessary to consult tribal governments, but to do so in a way that is widely encompassing and to err on the side of consulting, rather than not. From the DOJ's own tribal consultation policy:

"The requirements of Executive Order 13175 and this Policy Statement generally will be construed liberally in favor of Consultation on any given policy as defined above with Tribal implications. Consultations may be organized in a variety of ways, from a single group discussion to a more iterative process involving a series of discussions. All decisions regarding whether and how to conduct a Consultation, or whether a given policy or topic has Tribal implications, will be coordinated with the Department's Office of Tribal Justice."

There are 574 federally recognized tribes and around 258 tribal law enforcement agencies. That is a large amount of affected tribal entities and a large impact. As such I ask that the DEA

withdraw the current rulemaking and begin the mandated tribal consultation process under EO 13175 and DOJ's own policy. The DOJ policy also requires notice at least 30 days before the date of consultation.

Additionally, 3 Native American organizations have submitted comment to the DOJ/DEA asking for tribal consultations. These include the Ho Chunk Nation, the Association of American Indian Affairs, and the Indigenous Cannabis Industry Association.

As such Panacea Plant Sciences requests the rulemaking at hand be:

- 1. Withdrawn; and conduct tribal consultation which begins with a publication of notice seeking tribal input before rulemaking. The rule can be re-submitted for public comment and hearings after this is done.
- B) The next issue at hand that must be dealt with is, the DEA's current rulemaking references the Regulatory Flexibility Act

Panacea Plant Sciences itself is a small business that qualifies under the Regulatory Flexibility Act to have consultation. PPS researches cannabis, does not have a DEA license, and has had to keep focus on hemp due to federal law, except when working with groups in other countries. Moving marijuana into schedule 3 from schedule 1, instead of de-scheduling will hurt PPS and give preferential treatment to those with DEA schedule 3 or other licenses.

There are hundreds to thousands of hemp farms that would qualify under similar circumstances. There are also universities and other entities which would qualify. As such there is ample reason to follow the Regulatory Flexibility Act.

From the Regulatory Flexibility Act:

"§ 602. Regulatory agenda

- (a) During the months of October and April of each year, each agency shall publish in the Federal Register a regulatory flexibility agenda which shall contain —
- (1) a brief description of the subject area of any rule which the agency expects to propose or promulgate which is likely to have a significant economic impact on a substantial number of small entities;
- (2) a summary of the nature of any such rule under consideration for each subject area listed in the agenda pursuant to paragraph (1), the objectives and legal basis for the issuance of the rule, and an approximate schedule for completing action on any rule for which the agency has issued a general notice of proposed rulemaking, and
- (3) the name and telephone number of an agency official knowledgeable concerning the items listed in paragraph (1).
- (b) Each regulatory flexibility agenda shall be transmitted to the Chief Counsel for Advocacy of the Small Business Administration for comment, if any.
- (c) Each agency shall endeavor to provide notice of each regulatory flexibility agenda to small entities or their representatives through direct notification or publication of the agenda in

 Filed: 02/17/2025 Page 200 of 214

publications likely to be obtained by such small entities and shall invite comments upon each subject area on the agenda.

(d) Nothing in this section precludes an agency from considering or acting on any matter not included in a regulatory flexibility agenda, or requires an agency to consider or act on any matter listed in such agenda."

We would like to let it be known that this rulemaking was not included on the DOJ or DEA Regulatory Flexibility Agenda. We would like the rulemaking withdrawn until this can be done.

As such Panacea Plant Sciences requests the rulemaking at hand be:

Withdrawn; and hold a small business and entity consultation which begins with a publication to that end prior to rulemaking in 2024 and potential final rulemaking in 2025.

- C) Panacea Plant Sciences disagrees with the proposed placement of marijuana in Schedule 3, and instead finds that it should rather be removed from control completely and de-scheduled.
- Although, international treaties may tie the United States to controlling marijuana, THC and other compounds; it is unlikely that this treaty violation will lead to any negative outcome. Canada has similarly moved to make marijuana a medicine and even went further to make it a regulated recreational item. There has been no backlash to this move and no consequences for them. As such the UN and the treaty parties are in effect silently complicit.
- If marijuana is placed into a schedule, it should rather than schedule 3, be placed into schedule 5 due to its relative safety.
- Additionally, cocaine was allowed as an unapproved by the FDA drug for medical use until 2019, when it was approved under branded formulations by several companies.

https://www.fda.gov/drugs/unapproved-drugs/fda-notification-regarding-cocaine-hydrochloride-solution-products

However, the allowance as an unapproved drug use, was via grandfathering, but that was on the principal that the cocaine was pure and always an exact item in the grandfathered drug formulations from prior to 1938. Cocaine is and was derived from a plant source, Erythroxylaceae coca, which produces several tropane alkaloids and other compounds. In fact, most cocaine is not pure cocaine, but rather a mixture of compounds extracted from the plant, unless chemically purified in a modern lab. This is important because there have been attempts to have marijuana allowed as a drug for medical use via the same grandfathering mechanism that allowed cocaine as an FDA unapproved drug to be used for medical use. However, the DEA/HHS/FDA denied that petition saying that they cannot verify the contents of the pre-1938 drug compounds as they are only labeled as marijuana flower or extract and not by compound (ie THC, CBD) However, again cocaine was allowed with unknown variation, but due to this same type of variation, this medical marijuana grandfather petition was denied.

https://www.regulations.gov/document/FDA-2011-P-0671-0001

- This and the move to block wider access to cocaine for medical use, but instead only allow pharmaceutical branded approved versions, appear to be a move to consolidate the wider industry and supply of medicines into a small group of companies and people.
- We make these points to argue that raw dried marijuana flower and marijuana/marijuana extract and/or tinctures should be allowed to be manufactured by DEA-licensed marijuana cultivators, manufacturers and compound pharmacies. Marijuana should then be allowed to be prescribed by doctors nationwide and filled by pharmacies.
- Grandfathering (exempting from DEA/FDA regulation) state medical cannabis producers would also be a potential option.
- Additionally, patients should be allowed to seek a prescription and if granted to seek a DEA license as a manufacturer and distributor/dispensary to cultivate/dispense their own medical cannabis, or to do so in a collective with other patients. Patients could also import from Canada if allowed.
- The DEA is currently entering into agreements with religious organizations and churches to allow for their cultivation/importation and use of schedule 1 substances. If these smaller, non-commercial organizations are being allowed to have DEA licenses, then there is no reason why such a similar scheme could not be developed to provide access to the medical patients in the United States that wish to have immediate access, and to control their own supply of medication.
- https://www.marijuanamoment.net/federal-settlement-will-allow-arizona-church-to-import-process-and-use-ayahuasca-as-religious-sacrament/
- If the DEA, FDA, HHS and related agencies do not either, approve raw cannabis/extracts/tinctures as a FDA approved medication, provide a grandfather option via FDA/DEA as unapproved, but allowed medications, or allow state medical cannabis to be federally legal, then this rule-making does nothing to provide access to patients, and is effectively worthless except that providing 280E tax relief for federally illegal state medical cannabis businesses. There will be no reduction in costs or difficulty for research by this rule-making either, the only effective difference for research in schedule 1-3 is which box is checked on forms.
- However, although marijuana as a botanical product and medicine may be safe, there are risks from marijuana and cannabis derivatives and products which has been seen in the public via the EVali, lung injury vaping outbreak in 2020, 2,800 people were harmed and 68 died.

https://www.yalemedicine.org/conditions/evali

This outbreak primarily affected cannabis and hemp markets. One of the problems is the lack of regulations and the often lax regulations at the state levels. This leads to unregulated flavors/terpenes/cutting agents, from non-cannabis sources being added. For example vitamin e acetate, creating issues in the lungs with Evali was cited

primarily via the acetate. However, companies in the hemp industry are now creating products with THC-O-Acetate that are inhaled, creating similar dangers.

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9813278/

Squalane was another large problem in Oregon, and other states. Squalane was sold by companies as a diluent.

 $\underline{https://mjbizdaily.com/oregon-cannabis-regulators-ban-additives-first-seen-in-vaping-crisis/}$

Mold and pesticides are also common in the state marijuana industry, and often under or un-reported. Testing is not done at the appropriate frequency and intensity for product safety. For example, Washington State only does pesticide testing of marijuana on random testing that takes years for every company to be tested. As such it took years for the state's marijuana regulator to find out that DDT derivative DDE had been identified in marijuana products, likely due to the farmland being used for other crops previously. A bulletin from the regulator on the issue can be found here: https://content.govdelivery.com/accounts/WALCB/bulletins/36473ba.

As such, PPS asks the government to regulate cannabis, hemp and marijuana products for safety, and use this rule-making to also apply the deeming rule under tobacco inhalation product rules to require the products to be held to the same standards of safety at a minimum if unscheduled.

However, if placed into Schedule 3, 4 or 5, due to the myriad problems with essentially, every state medical or recreational marijuana and hemp programs, PPS asks the government to regulate medical marijuana standards at a federal level so that the country has a consistent, fair, safe market for patients and business.

D) The DEA ALJ we believe is unconstitutional as similar ALJ schemes have been found so by the supreme court. As such we believe that this rule-making should if hearings are held, be heard instead of the ALJ in federal court. Also there are Chevron deference issues. These all likely are being addressed, while indirectly, in the Supreme Court via the Jarkesy v SEC lawsuit. As such we hold that the currently rule-making should be stayed until the Jarkesy ruling is final.

Further evidence and information will be presented in the future. All notices to be sent pursuant to the proceeding should be addressed to:

Panacea Plant Sciences C/O David Heldreth

14321 Se 49th St

Bellevue WA 98006

Respectfully yours, David Heldreth Jr. for PPS

USCA Case #24-1365 Document #2100970 Filed: 02/17/2025 Page 204 of 214

September 16, 2024

Drug Enforcement Administration,

Attn: Administrator- DEA Federal Register Representative/DPW- Hearing Clerk/OALJ

8701 Morrissette Drive, Springfield, Virginia 22152.

Subject: Request for Hearing

Dear Sir:

The undersigned David Heldreth hereby requests a hearing in the matter of: DEA rule proposal: Schedules of Controlled Substances: Rescheduling of Marijuana also identified as Docket No. DEA-1362 and A.G. Order No. 5931-2024.

(1) state with particularity the interest of the person in the proceeding; (2) state with particularity the objections or issues concerning which the person desires to be heard; and (3) state briefly the position of the person with regard to the objections or issues.

I would like to verify standing in the rule-making by asserting that:

- 1.) David Heldreth is currently not licensed by the DEA.
- 2.) David Heldreth uses cannabis for nerve pain and related issues. Moving marijuana and related items to schedule 3 will not increase my access to the use of THC/marijuana and related items for medical use. Rather the government/HHS/FDA/DEA should have, based on the evidence found it should be de-scheduled. In fact moving to schedule 3 could lead to push to force state legal market buyers into federal legal system, which would cause crackdowns on state medical and recreational cannabis/marijuana which would lead to a reduction in availability and increase in cost or other detrimental effects.
- 3.) David Heldreth has research, IP and patent filings that incorporate marijuana, cannabis, THC and related items. This change in schedule has the possibility of lowering the valuation of patents and other IP. As such I will be heavily impacted by this process and rule-making.
- 4.) PPS and David Heldreth are the only public parties with experience in all 3 of the drug scheduling hearings that have occurred since 2020, regarding DOI, DOC and the 5 tryptamines. We have extensive knowledge and history with scheduling proceedings and are the most experienced group in the country in such hearings. DH should likewise be selected for the hearing.
- 5.) David Heldreth will be harmed if marijuana is moved into Schedule 3 instead of being descheduled and will be disadvantaged compared to those people and entities that have Schedule 3 licensing. Rather than schedule 3, marijuana should be de-scheduled.

Now in regards to the current rule-making, let us begin:

A) To start there are apparent errors in the rulemaking process, in that the DEA did not consult with tribal governments as required under Executive Order 13175.

The rulemaking references active Executive Order 13175 - Consultation and Coordination with Indian Tribal Governments – however, it asserts that no such consultation with tribal governments is necessary, or as stated directly below:

"This proposed rule does not have tribal implications warranting the application of <u>E.O. 13175</u>. It does not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes."

This statement is incorrect as this rulemaking will change the status of a substance under federal law from Schedule 1 to Schedule 3 it will then as such require changes to tribal law enforcement, tribal health care via independent or Indian Health Services, and other programs. Reservations are regulated as federal lands and many tribal law codes reference federal law and the Controlled Substances Act. As such the current rulemaking will create a situation in which tribal governments and law enforcement will be required to train law enforcement on the new laws and this alone will impose direct costs on tribal entities and governments. Additionally, the costs of any enforcement of these new laws incurred from arrests, testing, jailing, etc. which falls on tribal governments again represent burdens and reasons for the DEA/Department of Justice to conduct a tribal consultation prior to rulemaking as is required under EO 13175. From the text:

"To the extent practicable and permitted by law, no agency shall promulgate any regulation that has tribal implications, that imposes substantial direct compliance costs on Indian tribal governments, and that is not required by statute, unless:

- (1) funds necessary to pay the direct costs incurred by the Indian tribal government or the tribe in complying with the regulation are provided by the Federal Government; or
- (2) the agency, prior to the formal promulgation of the regulation,
- (A) consulted with tribal officials early in the process of developing the proposed regulation;
- (B) in a separately identified portion of the preamble to the regulation as it is to be issued in the **Federal Register**, provides to the Director of OMB a tribal summary impact statement, which consists of a description of the extent of the agency's prior consultation with tribal officials, a summary of the nature of their concerns and the agency's position supporting the need to issue the regulation, and a statement of the extent to which the concerns of tribal officials have been met; and
- (C) makes available to the Director of OMB any written communications submitted to the agency by tribal officials."

Additionally, under the current DOJ tribal consultation policy, the DEA and DOJ are tasked to not narrowly define when it is necessary to consult tribal governments, but to do so in a way that is widely encompassing and to err on the side of consulting, rather than not. From the DOJ's own tribal consultation policy:

"The requirements of Executive Order 13175 and this Policy Statement generally will be construed liberally in favor of Consultation on any given policy as defined above with Tribal implications. Consultations may be organized in a variety of ways, from a single group discussion to a more iterative process involving a series of discussions. All decisions regarding whether and how to conduct a Consultation, or whether a given

policy or topic has Tribal implications, will be coordinated with the Department's Office of Tribal Justice."

There are 574 federally recognized tribes and around 258 tribal law enforcement agencies. That is a large amount of affected tribal entities and a large impact. As such I ask that the DEA withdraw the current rulemaking and begin the mandated tribal consultation process under EO 13175 and DOJ's own policy. The DOJ policy also requires notice at least 30 days before the date of consultation.

Additionally, 3 Native American organizations have submitted comment to the DOJ/DEA asking for tribal consultations. These include the Ho Chunk Nation, the Association of American Indian Affairs, and the Indigenous Cannabis Industry Association.

As such David Heldreth requests the rulemaking at hand be:

- 1. Withdrawn; and conduct tribal consultation which begins with a publication of notice seeking tribal input before rulemaking. The rule can be re-submitted for public comment and hearings after this is done.
- B) The next issue at hand that must be dealt with is, the DEA's current rulemaking references the Regulatory Flexibility Act

David Heldreth is a shareholder in Panacea Plant Sciences, itself is a small business that qualifies under the Regulatory Flexibility Act to have consultation. PPS researches cannabis, does not have a DEA license, and has had to keep focus on hemp due to federal law, except when working with groups in other countries. Moving marijuana into schedule 3 from schedule 1, instead of de-scheduling will hurt PPS and give preferential treatment to those with DEA schedule 3 or other licenses.

There are hundreds to thousands of hemp farms that would qualify under similar circumstances. There are also universities and other entities which would qualify. As such there is ample reason to follow the Regulatory Flexibility Act.

From the Regulatory Flexibility Act:

"§ 602. Regulatory agenda

- (a) During the months of October and April of each year, each agency shall publish in the Federal Register a regulatory flexibility agenda which shall contain —
- (1) a brief description of the subject area of any rule which the agency expects to propose or promulgate which is likely to have a significant economic impact on a substantial number of small entities;
- (2) a summary of the nature of any such rule under consideration for each subject area listed in the agenda pursuant to paragraph (1), the objectives and legal basis for the issuance of the rule, and an approximate schedule for completing action on any rule for which the agency has issued a general notice of proposed rulemaking, and
- (3) the name and telephone number of an agency official knowledgeable concerning the items listed in paragraph (1).

USCA Case #24-1365 Document #2100970

Filed: 02/17/2025

- (b) Each regulatory flexibility agenda shall be transmitted to the Chief Counsel for Advocacy of the Small Business Administration for comment, if any.
- (c) Each agency shall endeavor to provide notice of each regulatory flexibility agenda to small entities or their representatives through direct notification or publication of the agenda in publications likely to be obtained by such small entities and shall invite comments upon each subject area on the agenda.
- (d) Nothing in this section precludes an agency from considering or acting on any matter not included in a regulatory flexibility agenda, or requires an agency to consider or act on any matter listed in such agenda."

We would like to let it be known that this rulemaking was not included on the DOJ or DEA Regulatory Flexibility Agenda. We would like the rulemaking withdrawn until this can be done.

As such David Heldreth requests the rulemaking at hand be:

Withdrawn; and hold a small business and entity consultation which begins with a publication to that end prior to rulemaking in 2024 and potential final rulemaking in 2025.

C) David Heldreth disagrees with the proposed placement of marijuana in Schedule 3, and instead finds that it should rather be removed from control completely and descheduled.

Although, international treaties may tie the United States to controlling marijuana, THC and other compounds; it is unlikely that this treaty violation will lead to any negative outcome. Canada has similarly moved to make marijuana a medicine and even went further to make it a regulated recreational item. There has been no backlash to this move and no consequences for them. As such the UN and the treaty parties are in effect silently complicit.

If marijuana is placed into a schedule, it should rather than schedule 3, be placed into schedule 5 due to its relative safety.

Additionally, cocaine was allowed as an unapproved by the FDA drug for medical use until 2019, when it was approved under branded formulations by several companies.

 $\frac{https://www.fda.gov/drugs/unapproved-drugs/fda-notification-regarding-cocaine-hydrochloride-solution-products}{}$

However, the allowance as an unapproved drug use, was via grandfathering, but that was on the principal that the cocaine was pure and always an exact item in the grandfathered drug formulations from prior to 1938. Cocaine is and was derived from a plant source, Erythroxylaceae coca, which produces several tropane alkaloids and other compounds. In fact, most cocaine is not pure cocaine, but rather a mixture of compounds extracted from the plant, unless chemically purified in a modern lab. This is important because there have been attempts to have marijuana allowed as a drug for medical use via the same grandfathering mechanism that allowed cocaine as an FDA-unapproved drug to be used for medical use. However, the DEA/HHS/FDA denied that petition saying that they cannot verify the contents of the pre-1938 drug compounds as they are only labeled as marijuana flower or extract and not by compound (ie THC, CBD) However, again cocaine was allowed with unknown variation, but due to this same type of variation, this medical marijuana grandfather petition was denied.

https://www.regulations.gov/document/FDA-2011-P-0671-0001

This and the move to block wider access to cocaine for medical use, but instead only allow pharmaceutical branded approved versions, appear to be a move to consolidate the wider industry and supply of medicines into a small group of companies and people.

Filed: 02/17/2025

- I make these points to argue that raw dried marijuana flower and marijuana/marijuana extract and/or tinctures should be allowed to be manufactured by DEA-licensed marijuana cultivators, manufacturers and compound pharmacies. Marijuana should then be allowed to be prescribed by doctors nationwide and filled by pharmacies.
- Grandfathering (exempting from DEA/FDA regulation) state medical cannabis producers would also be a potential option.
- Additionally, patients should be allowed to seek a prescription and if granted to seek a DEA license as a manufacturer and distributor/dispensary to cultivate/dispense their own medical cannabis, or to do so in a collective with other patients. Patients could also import from Canada if allowed. The DEA is currently entering into agreements with religious organizations and churches to allow for their cultivation/importation and use of schedule 1 substances. If these smaller, non-commercial organizations are being allowed to have DEA licenses, then there is no reason why such a similar scheme could not be developed to provide access to the medical patients in the United States that wish to have immediate access, and to control their own supply of medication.

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https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9813278/

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https://mjbizdaily.com/oregon-cannabis-regulators-ban-additives-first-seen-in-vaping-crisis/

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Further evidence and information will be presented in the future. All notices to be sent pursuant to the proceeding should be addressed to:

David Heldreth

14321 Se 49th St

Bellevue WA 98006

Respectfully yours,

David Heldreth Jr.

Drug Enforcement Administration, Attn: Hearing Clerk/OALJ 8701 Morrissette Drive, Springfield, VA 22152

Subject: Notice of Appearance

Dear Sir:

Please take notice that Emily Fisher will appear in the matter of: <u>Docket No. DEA-1362</u>; RIN 1117-AB77.

- (A) As CEO of Leafwell, I have a significant interest in the proceedings as Leafwell's operations are directly impacted by DEA regulations governing the use and distribution of medical cannabis. Leafwell, a leading telehealth organization specializing in medical cannabis consultations and patient education, operates across multiple states, providing critical healthcare services to a diverse patient population of over 400,000, many of whom rely on medical cannabis for managing chronic conditions. Our interest in this proceeding stems from the need to ensure that DEA policies are informed by the most current and comprehensive data on medical cannabis efficacy and safety.
- (B) We wish to address several key issues: Recognition of Medical Cannabis Efficacy: There is substantial evidence supporting the efficacy of medical cannabis in treating chronic pain, chemotherapy-induced nausea and vomiting, and multiple sclerosis spasticity. These findings are crucial for shaping any policy or regulatory changes. Impact on Healthcare Utilization: Leafwell's internal data indicates a significant reduction in the use of prescription medications, including opioids, anti-anxiety medications, and sleep aids, among patients who utilize medical cannabis. This shift in healthcare utilization should be considered when assessing the broader implications of cannabis regulation. Public Health and Safety: The reduction in opioid-related hospitalizations in states with medical cannabis laws highlights the public health benefits of accessible cannabis treatments. We believe these benefits should be central to any regulatory discussion. Leafwell conducted the largest study of pediatric medical cannabis users to date, analyzing nearly 14,000 patient records of individuals under 21. The study aims to provide a comprehensive understanding of medical cannabis use among young patients, highlighting the need for pediatric-specific evidence, clinical guidelines, and safer regulatory frameworks. (Doucette, Mitchell L., et al. "Medical Cannabis Use in Youth Under 21: Leafwell Study." Health Economics and Outcomes Research Division, Leafwell.)
- (C) Leafwell advocates for a regulatory framework that recognizes the demonstrated benefits of medical cannabis as evidenced by both national studies and our own patient data. We support policies that expand access to medical cannabis and integrate its use into mainstream healthcare practices. We believe that any restrictions or changes to current cannabis regulations should be carefully weighed against the substantial evidence of its efficacy and the potential for improved patient outcomes and reduced reliance on more harmful medications.

All notices to be sent pursuant to this appearance should be addressed to:

Emily Fisher, CEO, Leafwell, Inc. 9100 South Dadeland Avenue, Suite 1701 Miami, Florida 33156

Respectfully yours,



[EXTERNAL] Hearing

From Poeboys Salvage <august@poeboyssalvage.com>

Date Tue 9/17/2024 2:37 PM

To NPRM <NPRM@dea.gov>; Adobe <august@poeboyssalvage.com>

I want to address the issue of my person being arrested in Texas. The DEA authorizes me to lawful possession of THC.

August Wakat P.O. Box 700202 Tulsa, OK 74170 (918) 381-5907 

[EXTERNAL] Marijuana Hearing

From Karen Ferguson kferguson@aacap.org

Date Wed 9/18/2024 3:57 PM

To NPRM NPRM NPRM NPRM NPRM NPRM NPRM <a href="mailto:kferguso

Good Afternoon,

Will there be an option for a participant to speak virtually at this hearing on December 2? AACAP has a content expert who would like to participate in the hearing but would prefer not to travel to DC during this timeframe.

Please let me know before the September 30 deadline to nominate participants. We appreciate that a hearing has been scheduled.

Many thanks, -Karen

Karen Ferguson
Deputy Director of Clinical Practice
American Academy of Child and Adolescent Psychiatry
3615 Wisconsin Avenue, NW
Washington, DC 20016
202.587.9670

www.aacap.org

CERTIFICATE OF SERVICE

I certify that this document was filed with the Court via the court's electronic filing system, on the 17th day of February, 2025, and an electronic copy was served on all counsel of record via the CM/ECF system on the same date. I further certify that I have mailed the foregoing document via first class mail, postage paid, to those parties or their counsel who are not registered through the CM/ECF system.

/s/Austin T. Brumbaugh

Filed: 02/17/2025

Austin T. Brumbaugh